EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: C. R. BARD, INC. PELVIC
REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL NO. 2187

THIS DOCUMENT RELATES TO ALL CASES

RULE 26 GENERAL LIABILITY EXPERT REPORT OF

DANIEL ELLIOTT, M.D

I am providing my expert opinion regarding the use of transvaginal synthetic mesh for pelvic organ prolapse (referred to herein as "POP") including the Avaulta Plus and Avaulta Solo products. The following represent my opinions, all held to a reasonable degree of medical probability and certainty. These opinions are based upon my background, training and experience as well as the totality of available data from all sources, which I have reviewed. My CV, fee schedule and testimony for last four years is being provided with this Report. The following is a summary of my opinions that I have formed.

I reserve the right to supplement this report if new or supplemental information is provided at any point, and as I review other related documents.

Dated: October 8, 2014.

Daniel S. Elliott, M.D.

I. BACKGROUNDS AND QUALIFICATIONS

I am an Associate Professor of Urology, section of Female Urology and Reconstructive Surgery, at Mayo Clinic Graduate School of Medicine in Rochester, Minnesota. My current curriculum vita, attached hereto as Exhibit "A", more fully and accurately reflects my training, background, academic activity and publications. However, briefly, I received an M.D. in 1993 from Loma Linda University School of Medicine in Loma Linda, California. Following graduation from medical school, I completed one year of General Surgery and five years of Surgical Urology residency at the Mayo Graduate School of Medicine at the Mayo Clinic in 1999. I then completed a one-year advanced surgical fellowship at Baylor College of Medicine in Houston, Texas, in Neurourology, Urodynamics and Voiding Dysfunction. I then re-joined the faculty at the Mayo Clinic, where I have spent the last fourteen years specializing in treating pelvic organ prolapse and urinary incontinence in women and urinary incontinence in men. I have published nearly 60 peer-reviewed articles and given over a 100 lectures nationally and internationally pertaining to urinary incontinence and pelvic organ prolapse. I have specifically authored two published scientific manuscripts dealing with polypropylene meshes in the animal model. A Mayo Clinic colleague and I were the first to perform robotic sacrocolpopexy surgery for the treatment of high-grade prolapse and to publish extensively on the subject and the first to perform and publish on the outpatient, non-mesh transobturator sling.

During my training, I was introduced to the use of synthetic midurethral slings for incontinence repair. I have used the Mentor OB/Tape products as well as mesh slings made by AMS and Coloplast. As of almost a year ago, I decided to no longer use meshes in my practice through the transvaginal route unless there is absolutely no other alternative. The reason that I made this decision is that my practice has become increasingly dedicated to treating a whole host of life-altering complications associated with the use of both SUI and POP meshes, including meshes made by Bard. Neither I, nor my colleagues at Mayo, have ever used transvaginal POP kits as we felt that the risk to patients was too great. Having

treated hundreds of patients with mesh-related complications (both SUI and POP), I feel that we made the right decision not to include them as part of our treatment regimen. I only use mesh for POP repair through robotic sacrocolpopexy as it is not a transvaginal surgery, uses much less mesh, and is associated with significantly fewer complications than are associated with transvaginal mesh prolapse repair.

I am a frequent invited national and international lecturer at medical and surgical conferences addressing stress urinary incontinence and pelvic organ prolapse, their evaluation, treatment, surgical options and management of complications. I have taken and passed the subspecialty credentialing process recently established by the combined boards of the American Board of Urology and American Board of Obstetrics and Gynecology in Female Pelvic Medicine and Reconstructive Surgery.

II. BASIS OF OPINIONS

I have been asked to provide opinions regarding the subject of pelvic organ prolapse, its evaluation, treatments, surgical options and management of complications as well as to address the actions of C.R. Bard, Inc., (Bard) regarding its transvaginal mesh pelvic floor repair products. The focus of my investigation for this report is on the Avaulta Plus and Avaulta Solo products. My opinions are based on my personal knowledge, experience, and my investigation in this case. All of my opinions, and the basis of these opinions, are true and correct to the best of my knowledge and belief, including those related to scientific and medical issues, which are true and correct to a reasonable degree of scientific and medical certainty. I do, however, reserve the right to supplement this report and my opinions in light of any additional material or information provided to me, including any reports submitted and/or any other discovery that is taken in this case. Furthermore, if called to testify, I would plan to use various demonstrative exhibits, animations, video recordings, and/or anatomic models to show the relevant anatomy and surgical procedures and to describe my opinions as set forth in this report. The materials I have reviewed and relied upon to form my opinions for this report are listed in

Exhibit "4" to this report.

III. SUMMARY OF OPINIONS

A. Bard's Avualta Plus and Avaulta Solo are unsafe and inappropriate for implantation in the pelvic floor to treat Pelvic Organ Prolapse for the following reasons:

1. The resin used to manufacture the polypropylene mesh in Avaulta Solo and Avaulta Plus should never have been used to manufacture a medical implant.

2. The polypropylene mesh in the Avaulta products degrades and is not inert. Bard failed to perform any tests to determine whether naturally occurring peroxide in a woman's vagina could cause degradation of the mesh.

3. The mesh in the Avaulta products shrinks and contracts.

4. The Pore Size in the polypropylene mesh used in the Avaulta products was inadequate to foster proper tissue in growth.

5. The arms of the Avaulta Solo and Avaulta Plus are unreasonably dense.

6. The design and implantation method causes the mesh to saw the tissues through which the arms are pulled.

7. The blind passage of the trocars to implant the Avaulta products is unsafe.

8. The blind passage of the trocars to implant the Avaulta products is unsafe.

9. Avaulta Plus's porcine collagen causes an even greater inflammatory response than the synthetic polypropylene mesh alone

10. Because of their Transvaginal implantation method, Avaulta Plus and Avaulta Solo have an abnormally high risk of adversely contaminating the surgical field with bacteria and other microbiotics.

11. Despite knowledge that removal of the mesh may be necessary under certain circumstances, Bard never developed a way to remove the mesh after it was implanted.

12. Safer alternative designs to the Avaulta Solo and Avaulta Plus were available when Bard began marketing them.

13. The design of the Avaulta Solo and Avaulta Plus with four arms and blind trocar implantation method is inherently flawed.

14. Bard failed to conduct any tests to determine risks of lasting complications patients would suffer as a result of the Avaulta Solo and Avaulta Plus.

15. Bard's animal testing was insufficient and not correlated to prove the safety and effectiveness of the Avaulta Solo and Avaulta Plus in humans.

16. Bard knew the deleterious effect of collagen material on wound healing. The worsening safety of uniting polypropylene and porcine collagen was known to Bard.

17. Despite knowledge about problems linked to the Avaulta Solo and Avaulta Plus, Bard never developed or communicated a contingency plan for managing them after the devices were implanted.

B. Bard failed to disclose pertinent adverse risk information, pertinent information about the defects in the properties of the mesh and the inadequacies regarding the system of implantation about its Avaulta products to physicians and their patients.

C. Plaintiffs have suffered and will continue to suffer because of the defects in the design of the Avaulta products and because of Bard's failure to disclose known adverse risk information and product defect information.

NORMAL ANATOMY AND PELVIC ORGAN PROLAPSE

The normal vagina is a functional, pliable, distensible, mobile, and well-supported structure. Pelvic organ prolapse (POP) is a condition in which one or more of the female pelvic organs (bladder, rectum, uterus, and/or intestines) drop into the vagina to varying degrees, as a result of weakened vaginal tissue to form a bulge or fullness in the vagina. POP can affect the quality of life (QOL) of women; however, POP is not a life-threatening condition. POP is for many women a normal part of the aging process and can result from some combination of increasing age, multiple childbirths, frequent heavy lifting, chronic cough, obesity, constipation, previous hysterectomy and genetic predisposition. Symptoms of POP are usually limited to QOL issues such as the sensation of pelvic fullness, pressure and interference with sexual activity. It can also impact on urination and bowel function. POP is a relatively common condition, with up to 50% of women who have had children having some degree of POP; however, only a fraction of those women are symptomatic. Medical device manufacturers such as

the manufacturer of the Avaulta Plus and the Avaulta Solo, Bar, perceived that the potential surgical market created a desirable target for device manufacturers eager to capture market share. (Wall L: The perils of commercially driven surgical innovation. Am J of Obstetrics and Gyne Jan 2010; 202.30e1-4).

As mentioned above, POP is a protrusion or a falling down of one or more of the pelvic organs into the vagina. This can affect one or more of the vaginal "compartments." These compartments are:

- The bladder (called an Anterior Compartment Prolapse or Cystocele).
- The rectum (called the Posterior Compartment Prolapse or Rectocele).
- The uterus (called Uterine Prolapse).
- The small intestines (called the Apical Compartment Prolapse or Enterocele).
- In cases where POP affects all of the compartments, this is often referred to as a Vaginal Vault Prolapse.

Treatment for female pelvic organ prolapse can be generally broken down into four main categories:

- Behavior modification & Pelvic Floor Therapy & Exercises
- Medication
- Pessary
- Surgical treatment

IV. TREATMENT FOR PELVIC ORGAN PROLAPSE

A. Traditional POP Treatment Options

There are multiple well-established treatment options for treating POP. A thorough understanding of the risks and benefits of each of the POP treatment options is imperative for the treating physician to evaluate and recommend appropriate therapy for each patient, since each patient represents unique characteristics, symptoms, and risk factors, which can affect the success and complications of any therapy. Following a thorough physical exam by a trained medical practitioner, the

severity and QOL impact of the POP is determined. Management options of POP can be broken down into several broad categories such as observation, behavioral therapies, pelvic floor exercises, pessary use, and, as a last resort, surgery. Since POP is primarily a QOL issue, the physician must first determine whether or not the POP is actually problematic for the patient. Many times the POP is mild and causes either no or only minimal symptoms. In this frequent situation, the safest treatment option is observation with periodic reevaluation to determine if the POP and the patient's symptoms progress or not. For the patient with more severe POP that is symptomatic, further conservative options should be considered such as behavioral changes (weight loss, lifestyle changes), pelvic floor exercises and/or the use of pessary devices.

Surgical procedures should usually be reserved for severe, high grade POP that is negatively and significantly impacting the QOL for the woman. Surgical repair of POP has been documented and has evolved over the years. Traditional surgery is performed from either the vagina (termed "transvaginal") or from the abdomen (termed "transabdominal"), with the latter group being performed either with an abdominal incision (Abdominal Sacrocolpopexy) or with minimally- invasive procedures such as with laparoscopic or robotic technology. The Avaulta procedure was developed as an alternative procedure to the traditional methods of treating prolapse. By definition, a comparison of the safety and effectiveness/risks and benefits of the Avaulta procedure with the alternatives requires a comparison with these traditional procedures.

B. Traditional, Transvaginal NON-Mesh POP Procedures.

Traditional transvaginal surgery for POP utilizes an incision through the wall of the vagina hence the term "transvaginal" literally meaning "through the vagina." It is imperative to recognize the basic difference between transvaginal and transabdominal (through the abdomen) surgery since the surgical route chosen affects success, complications, and QOL results.

Traditional non-mesh transvaginal surgery relies on the mobilization and the stitching together of the patient's own deep vaginal tissues (also known as "native tissue") to support the vagina and to repair the POP. Traditional transvaginal surgery for POP, in contrast to Avaulta Systems, does NOT utilize the blind passage of trocars or mesh in its repair.

One of the most significant arguments used by mesh manufacturers to justify vaginal mesh use over the traditional, non-mesh POP repairs was the misconceived notion that traditional repairs had failure rates of up to 30-40%. This failure rate was based primarily on the work of the 2001 National Institutes of Health (NIH) Workshop on Standardization of Terminology for Researchers in Pelvic Floor Disorders. However, since the Workshop's recommendations in 2001, there have been significant advancements in the understanding of what is normal vaginal support, pelvic prolapse, POP symptoms, and the very critical issue of what patients perceive as a successful outcome following POP surgery. What is now apparent is that the NIH POP Workshop grading system was so strict that a large percentage of average healthy women would fail if graded under that system. This misconception has now been recognized in the medical literature. Currently, within contemporary POP studies which utilize up-to-date prolapse definitions, the accepted failure rate of traditional, non-mesh POP repairs is less than 15% and closer to 12%.[1,2,3]

C. Transabdominal/Laparoscopic/Robotic POP Repair

Sacrocolpopexy is a procedure performed through the abdomen. Although not without risk, sacrocolpopexy is superior to transvaginal mesh procedures as it offers a greater chance of long-term anatomical and symptomatic POP success, with fewer risks. Traditionally, this approach utilized an incision in the lower abdomen. However, with the advancement of minimally-invasive procedures such

[1] Weber AM, Walters MD, Peidmonte MR et al: Anterior Colporraphy: A randomized trial of three surgical techniques. Am J Obstet Gynecol (2001) 185(6):1299-304; discussions 1304-6. 172.
[2] Weber AM, Abrams P, Brubaker L: The standardization of terminology for researchers in female pelvic floor disorders. Int Urogynecol J (2001) 12:178-186.
[3] Chmielewski L, Walters MD, Weber AM, et al: Reanalysis of a randomized trial. J ObstetGynecol (2011) 205:96.e1-8.

as laparoscopy and robotic surgery, the procedure is increasingly performed using these less invasive alternatives. In the past, the sacrocolpopexy was reserved for the treatment of more severe vaginal vault prolapse or recurrent POP following a failed previous surgery. The procedure entails stitching a mesh or biomaterial to the top, apex and bottom of the vagina then stitching that same mesh or biomaterial to the large bones at the base of the spine called the sacrum.

D. History of Synthetic Mesh

Abdominal and thoracic wall weaknesses, called hernias, exist due to inherent weaknesses within the abdominal wall or thoracic wall due to conditions such as birth defects, surgery, and radiation effects. Traditional hernia repair surgery evolved using sutures (stitches) to bring the native tissue together. However, due to the inherent weaknesses of the tissues, failure was common and frequently resulted in significant pain and suffering for the patient. Therefore, in the 1950's, surgical meshes for hernia repairs were introduced. Subsequently, academic presentations, surgical reports and journal manuscripts began to describe mesh-related complications such as chronic pain, abdominal wall rigidity, mesh contraction, infection, fistula formation, recurrence and chronic inflammatory process.[4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22]

[4] Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan; 2(1):103-17.
[5] Agresta F, Baldazzi G, Ciardo et al: Lightweight partially absorbable monofilament mesh (polypropylene/poliglecaprone 25) for TAPP inguinal hernia repair. Surg Laparosc Endosc Percutan tech 2007, 17; 91- 94.
[6] Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia (1997) 1:15-21.
[7] Bellon J, Honduvilla N, Jurado F et al: In vitro interaction of bacteria with polypropylene/ePTFE prostheses. Biomaterials. 2001 Jul; 22(14):2021-4.
[8] Bouikerrou M, Boulanger L, Rubod C et al: Study of the biomechanical properties of synthetic implanted in vivo. European J. Obstet & Gynecol and Repro Bio 134: (2007)262-267.
[9] Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. European Journal of Surgery Volume 164, Issue 12, pages 965–969, December 1998.
[10] Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg. 1999 Jul; 165(7):665-73.
[11] Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. J. Surgical Research 103, 208-214 (2002).
[12] Klosterhalfen B, Klinge W, Schumpelick V: Functional and morphological evaluation of different polypropylene- mesh modifications for abdominal wall repair. Biomaterials. 1998 Dec; 19(24):2235-46.

An abundant amount of evidence in the medical literature and basic science data has been gathered over the past two decades that indicates that there is a strong and direct relationship between postoperative mesh complications and mesh design.[23, 24, 25, 26, 27, 28, 29, 30] Reducing mesh-related complications demands a thorough understanding and knowledge of the chemical, physical and synthetic characteristics of meshes and how they react inside the human body. Based upon vast amounts of general surgery and basic science literature, there is a consensus that synthetic meshes that are lower weight (less surface area), larger pore size, higher porosity, monofilament, and that are capable of maintaining their elasticity and structural stability during and after implantation will have better results

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[13] Krause H, Galloway S, Khoo S et al: Biocompatible properties of surgical mesh using an animal model. Aust N Z J Obstet Gynaecol. 2006 Feb; 46(1):42-5.
[14] Mamy L, Letouzey V, Lavigne J et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. Int Urogynecol J. 2011 Jan; 22(1):47-52.
[15] Garcia M, Ruiz V, Godoy A, et al: Differences in polypropylene shrinkage depending on mesh position in an experimental study. American Journal of Surgery Vol 193, Issue 4, April 2007, p538-542.
[16] Cappelletti M, Attolini G, Cangioni G, et al. The use of mesh in abdominal wall defects. Minerva Chir. 1997 Oct; 52(10):1169-76.
[17] Klosterhalfen B, Klinge W, Hermanns B et al: Pathology of traditional surgical nets for hernia repair after long- term implantation in humans. [ABSTRACT] Chirugr 2000; 71:43-51.
[18] Seker D, Kulacoglu H. Long-term complications of mesh repairs for abdominal wall hernias. J Long Term Eff Med Implants. 2011; 21(3):205-18.
[19] Cobb W, Burns J, Peindl R et al: Textile analysis of heavy weight, mid-weight, and light weight polypropylene mesh in a porcine ventral hernia model. J Surgical Research 136, 1-7 (2006).
[20] Pandit A, Henry J. Design of surgical meshes - an engineering perspective. Technol Health Care. 2004; 12(1):51- 65.
[21] Pierce L, Grunlan M, Hou Y et al: Biomechanical properties of synthetic and biologic graft materials following long-term implantation in the rabbit abdomen and vagina. Am J Obstet Gynecol. 2009 May; 200(5):549.e1-8.
[22] Costello C, Bachman M, Grand, S, et al. Characterization of heavyweight and lightweight polypropylene prosthetic mesh explants from a single patient. Surg Innov. 2007Sep; 14(3):168-76.
[23] Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan; 2(1):103-17.
[24] Agresta, F, Baldazzi G, Ciardo et al: Lightweight partially absorbable monofilament mesh (polypropylene/poliglecaprone 25) for TAPP inguinal hernia repair. Surg Laparosc Endosc Percutan Tech 2007, 17; 91- 94.
[25] Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia (1997) 1:15-21.
[26] Bellon J, Honduvilla N, Jurado F et al: In vitro interaction of bacteria with polypropylene/ePTFE prostheses. Biomaterials. 2001 Jul; 22(14):2021-4.
[27] Bouikerrou M, Boulanger L, Rubod C et al: Study of the biomechanical properties of synthetic implanted in vivo. European J. Obstet & Gynecol and Repro Bio 134: (2007)262-267.
[28] Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. European Journal of Surgery Volume 164, Issue 12, pages 965–969, December 1998.
[29] Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg. 1999 Jul; 165(7):665-73.
[30] Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. J. Surgical Research 103, 208-214 (2002).

with fewer complications. Of all the mesh characteristics, pore size and stability of the mesh are among the most important.

E. Synthetic Mesh Use in Urogynecology

1. Sacrocolpopexy

Synthetic meshes are used transabdominally in sacrocolpopexy. Sacrocolpopexy can now be performed using laparoscopic and robotic technologies. Although mesh is used in sacrocolpopexy, there are important distinctions between the two procedures. As explained above, the mesh used in sacrocolpopexy is inserted through the sterilized transabdominal approach whereas in the transvaginal procedure, the mesh passes through the "clean *contaminated"* environment of the vagina and therefore is exposed to bacteria and other pathogens during and after implantation.

The amount of mesh used in sacrocolpopexy is significantly less than that typically used in the Avaulta procedure and other transvaginal mesh POP repair procedures. The anatomical location of the mesh and the forces applied to the mesh during implantation also differ between the two procedures. In sacrocolpopexy, the mesh does not need to be inserted through the use of cannulas and is therefore much less likely to experience folding or roping during insertion. Unlike transvaginal procedures which are done blindly through the use of trocars, sacrocolpopexy allows the surgeon to visualize the placement of the mesh which avoids the risks of blind passage. For all of these reasons, the risk profile of sacrocolpopexy is superior to that of transvaginal mesh kits for Avaulta Plus and Avaulta Solo.

2. Transvaginal Mesh Kits for POP

Use of transvaginal synthetic mesh for POP repair was marketed mainly as a way to increase the durability of the POP repair relative to the misperceived higher failure rate of traditional, non-mesh transvaginal POP surgery. A brief comparison is warranted between the traditional, transvaginal non-mesh POP surgery and the prepackaged mesh kits in order to understand the new and unique treatment alternative the mesh kits represented upon their introduction to the marketplace. The general similarities

between traditional, transvaginal and mesh kit POP procedures are:

- Both are designed to treat POP;
- At the time of surgery, the patient is placed in the same position on the operating table;
- The procedures are done under either general or spinal anesthetic;
- The procedures are performed through the vagina; and,
- A cystoscopy is required when performing an anterior or apical repair to rule out inadvertent bladder injury. Traditional non-mesh transvaginal POP surgery diverges from mesh kit procedures at this point. Typically, traditional surgery, instead of using a synthetic mesh to hold up the prolapsing pelvic organ, uses only sutures (also called stitches) placed into the native tissues surrounding the prolapsing portion of the vagina to repair the POP. These stitches are placed under direct vision, meaning the surgeon can visualize where the stitch is going, thereby reducing the risk of injury to surrounding tissues and pelvic organs. In general, there are several broad, though very important differences between traditional, transvaginal non-mesh and mesh kit POP surgeries:
- No synthetic, non-absorbable meshes are used in traditional POP surgery;
- No trocars/guides are used to place the mesh into position in traditional POP surgery;
- There is no tensioning of mesh arms with traditional surgery, and;
- The traditional procedure is performed under direct vision, meaning that the surgeon can see what he/she is doing with no blind passing of trocars.

V. BARD MESH

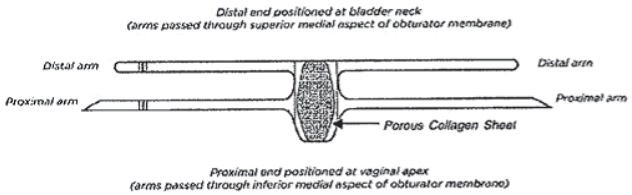
A. AVAULTA SOLO AND AVAULTA PLUS GENERAL PRODUCT DESCRIPTION AND METHOD OF IMPLANTATION

The Avaulta Plus Organ Prolapse repair system is a synthetic polypropylene mesh. Avaulta Solo Pelvic Organ Prolapse repair system is also a synthetic polypropylene mesh but with a piece of porcine collagen attached to it. Both systems are implanted through an incision in a woman's vagina, i.e. transvaginally, using trocars (surgical needles) that are specifically designed for each repair system. As depicted below, each version of the Avaulta Plus and Avaulta Solo Pelvic Organ Prolapse repair systems has a main mesh area, with four arms projecting from it. There are two version of each

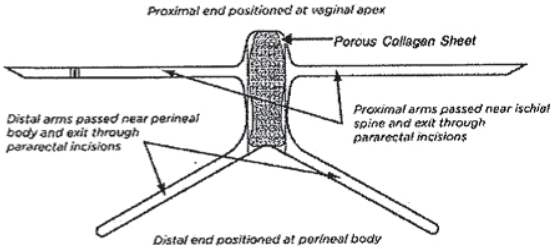
product: one for anterior repair and another for posterior prolapse repair. Both versions of the Avaulta Plus and Avaulta Solo products look like this:

AVAULTA PLUS

Anterior

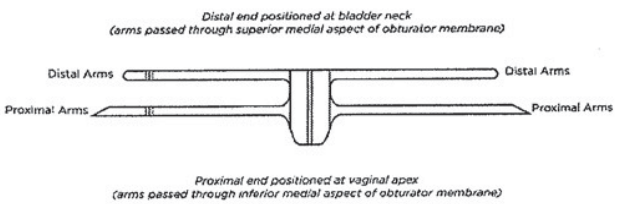


Posterior

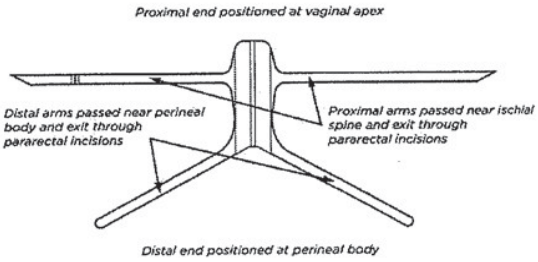


AVAULTA SOLO

Anterior



Posterior



The surgeon places each of these products through a "blind passage." In other words, the surgeon cannot see where the trocars are cutting and cannot see the channels incised by the trocars. To place the mesh, the surgeon must first push the trocars into the pelvic floor, cutting channels with the trocars inwardly around and/or through vital organs and structures, such as the perineal skin, obturator foramen, obturator internus, levator ani, among several others, and then out by way of a mid-vaginal incision. The surgeon then attaches the mesh arms to the trocar tip and, through rounded channels cut by the trocars, the flat arms are pulled through the pelvic floor and its vital structures, including near to the ischial spine and the junction of the superior and inferior pubic rami, among others, and outward into

place, stationing the mid portion of the mesh either between the bladder and anterior vaginal wall (anterior Avaulta), or between the rectum and the posterior vaginal wall (posterior Avaulta). As the surgeon pulls the Avaulta flat mesh arms with the trocar through the smaller, rounded trocar cut channels, the tension that is created along the mesh arm causes it to deform by curling and roping, among other deformations. These deformations alter not only the shape of the arms at the point of contact, but also the size and shape of the pores on the mesh. With the arms acting as fixation points, the surgeon is supposed to attach the arms to the left and right pelvic sidewall muscles: the obturator internus and levator ani proximally and distally. Affixed in this way, the arms are supposed to provide support for the central portion of the Avaulta mesh, which in turn supports the anterior and posterior walls of the vagina and thus repairs the prolapse.

VI. AVAULTA SOLO AND AVAULTA PLUS ARE NOT SAFE OR APPROPRIATE FOR IMPLANTATION IN THE PELVIC FLOOR FOR THE TREATMEN OF PELVIC ORGAN PROLAPSE

The design of the Avaulta Plus and Avaulta Solo products are not safe for use in the treatment of pelvic organ prolapse for numerous reasons, including, but not limited to the following:

1. The resin used to manufacture the polypropylene mesh in Avaulta Solo and Avaulta Plus should never have been used to manufacture a medical implant.

Bard used Phillips Sumika's resin[31] to make the polypropylene mesh contained in the Avaulta Plus.[32] The Material Safety Data Sheet dated February 13, 2008, clearly notes the polypropylene resin should not have been used for human medical device implant applications, as it states:

> "Do not use this Phillips Sumika Polypropylene Company material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues."

[31] Marlex HGX-030-01 was manufactured for use in woven industrial fabric and bags, rope and cordage, woven carpet backing and woven geotextile fabrics. (AVA2E00607485)
[32] AVA20626470; 5/10/2013 Britton deposition, pp. 35-6.

> "Do not use Phillips Sumika Polypropylene Company material in medical applications involving brief or temporary implantation in the human body or contact with internal body fluids or tissues unless the material has been provided directly from Phillips Sumika Polypropylene Company under an agreement which expressly acknowledges the contemplated use. Phillips Sumika Polypropylene Company makes no representation, promise, express warranty or implied warranty concerning the suitability of this material for the use in implantation in the human body or contact with internal body fluids or tissues." (AVA2E1281085).

From internal documents it appears that Bard intentionally hid the use of this resin from the supplier.[33]

The Marlex HGX-030-01 polypropylene used in the manufacture of the Avaulta Plus and Avaulta Solo products does not meet medical requirements. It is not made or intended for human implantation, and is in fact, expressly forbidden from use for permanent human implantation. This material is known to be subject to embrittlement, hardening and degradation within the human body. The material is incompatible with and will react with oxygen and oxidizing agents, several of which are known to be very prevalent inside the body, including oxygen and peroxides. The inadequacies of the mesh leads to long term complications, including, among others, erosion, chronic pain, nerve entrapment, pain syndromes, sexual dysfunction, chronic dyspareunia, loss of elasticity, mesh contraction, organ dysfunction, voiding dysfunction, muscle and nerve damage, vaginal scarring, the need for multiple surgeries, inability to remove the mesh and irreversible life-long complications.

2. The polypropylene mesh in the Avualta products degrades and is not inert. Bard never conducted testing to determine whether peroxide naturally occurring in the vagina could lead to degradation of the mesh.

Long before Bard began to design and market Avaulta Solo and Plus, it knew or should have known that polypropylene mesh is not inert and is subject to degradation inside the body. Study after study from as early as 1976, showed that even only a few days exposure polypropylene degraded in vivo

[33] AVA2E8262831-834 (email chain dated March 31, 2004, written by William Grennan to Thiemo Blank and Roger Davis discussing the fact that the supplier does not know of medical application and to purchase through a third party to avoid discovery of medical application.)

from oxidation.[34] By 1982, another article similarly discussed that free radicals can deteriorate polypropylene, altering its molecular weight, mechanical properties and even its crystalline structure.[35] As late as 1994, still years before Bard marketed Avaulta Solo and Avaulta Plus, another article suggested that the process of oxidation will increase tissue damage due to invading organisms.[36] In another 1994 article, the authors similarly explained the "vicious cycle" between foreign body response to a polymer implant material and degradation.[37] This article further described how stress on the polymer can impact degradation, explaining that "[m]echanical stress may affect degradation either as a result of loading under service, or because of residual stress arising during manufacturing."[38]

In a 2006, an article relating to a study of explanted polypropylene hernia meshes, the authors discussed the mechanisms and harmful effects of the degradation of polypropylene inside the body.[39] More recently, another article on a study of one hundred explanted polypropylene meshes, concluding that implants degrade more in the presence of chronic inflammation. [40]

Despite knowledge that the naturally occurring peroxides in a woman's pelvis and the foreign body reaction could degrade the mesh, Bard never studied whether and to what degree it would. Bard clearly had then no scientific basis to claim that it would not or that the mesh was inert and would remain so after implantation.

As polypropylene degrades, the inflammatory response increases and intensifies.[41] The abraded

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[34]Liebert, T.C., et al., *Subcutaneous implants of polypropylene filaments*. **J. Biomed. Mater. Res.**, Vol. 10, 939-951 (1976).
[35] Williams, D.F., *Review Biodegradation of surgical polymers*, **Journal of Materials Science**, Vol. 17, 1233-46 (1982).

[36] Ali, S.A.M., et al., *The Mechanisms of Oxidative Degradation of Biomedical Polymers by Free Radicals*, **Journal of Applied Polymer Science**, Vol. 51, 1389-98 (1994).
[37]Zhong, S.P., et al., *Biodeterioration/Biodegradation of Polymeric Medical Devices In Situ*, **International Biodeterioration& Biodegradation**, Vol. 130, 95 (1994).
[38]*Id.*, p. 108.
[39]Costello, C.R., et al., *Materials Characterization of Explanted Polypropylene Hernia Meshes*, **J. of Biomedical Mater. Res. Part B: Applied Biomaterials**, Vol. 83B(1), 44-49 (2007) (**Exhibit 31**).
[40] Clave, et. al., Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. Int Urogynecol J 2010 Mar; 21(3):261-70.
[41] Mamy L, Letouzey V, Lavigne J et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. Int Urogynecol J. 2011 Jan;22(1):47-52; Boulanger L, Moukerrou M et al. Bacteriological

fiber surface increases the surface area of the mesh, provides multiple areas that can effectively harbor bacteria, and creates a "barbed-wire" effect, all of which lead to an increased risk of an enhanced and chronic inflammatory response, as well as chronic infections due to bacterial proliferation at the mesh surface. The degradation of the mesh leads to long term complications, including, among others, erosion, chronic pain, nerve entrapment, pain syndromes, sexual dysfunction, chronic dyspareunia, loss of elasticity, mesh contraction, organ dysfunction, voiding dysfunction, muscle and nerve damage, vaginal scarring, the need for multiple surgeries, inability to remove the mesh and irreversible life-long complications.

3. The mesh in the Avualta products shrinks and contracts.

Polypropylene surgical mesh is known to contract and shrink when placed in the body.[42] [43] [44] [45] [46] [47] [48] [49] [50] [51] [52] [53] Mesh contraction and shrinkage leads to long term complications,

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analysis of meshes removed for complications after surgical management of urinary incontinence or pelvic organ prolapse. Int Urogynecol J (2008) 19:827-831; Bellon J, Honduvilla N, Jurado F et al: In vitro interaction of bacteria with polypropylene/ePTFE prostheses. Biomaterials. 2001 Jul; 22(14):2021-4.

[42] Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia (1997) 1:15-21.

[43] Bouikerrou M, Boulanger L, Rubod C et al: Study of the biomechanical properties of synthetic implanted in vivo. European J. Obstet & Gynecol and Repro Bio 134: (2007) 262-267.

[44] Boukerrou M, Rubod C, Dedet B et al: Tissue resistance of free tension procedure: What about healing? Int Urogynecol J (2008) 19:397-400. Published online Sept 2007.

[45] Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg. 1999 Jul; 165(7):665-73.

[46] Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. European Journal of Surgery Volume 164, Issue 12, pages 965–969, December 1998.

[47] Klosterhalfen B, Klinge W, Schumpelick V: Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair. Biomaterials. 1998 Dec; 19(24):2235-46.

[48] Klosterhalfen B, Klinge W, Hermanns B et al: Pathology of traditional surgical nets for hernia repair after long- term implantation in humans. [ABSTRACT] Chirugr 2000; 71:43-51.

[49] Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan; 2(1):103-17.

[50] Krambeck A, Dora C, Elliott D. Time-dependent variations in inflammation and scar formation of six different pubovaginal sling materials in the rabbit model. Urology. 2006 May; 67(5):1105-10.

[51] Krause H, Galloway S, Khoo S et al: Biocompatible properties of surgical mesh using an animal model. Aust N Z J Obstet Gynaecol. 2006 Feb; 46(1):42-5.

[52] Hilger W, Walter A, Zobitz M et al: Histological and biomechanical evaluation of implanted graft materials in a rabbit vaginal and abdominal model. Am J Obstet Gynecol 2006; 195:1826-31.

including, among others, erosion, chronic pain, nerve entrapment, pain syndromes, sexual dysfunction, chronic dyspareunia, loss of elasticity, mesh contraction, organ dysfunction, voiding dysfunction, muscle and nerve damage, vaginal scarring, the need for multiple surgeries, inability to remove the mesh and irreversible lifelong complications.

The reported incidence (which likely underestimates the degree of the problem) of shrinkage and contraction ranges from 11 to 20%. However, because of multiple varying factors such as reporting variations, under-reporting, short-term reporting, patient and physician ignorance, and delayed presentation, it is impossible to know the true incidence and severity of vaginal mesh contraction.[54] [55] [56] [57] [58] [59] [60] [61] [62] [63] [64] [65] [66] [67] [68] [69] [70] [71]. Feiner and Maher evaluated 17 women with

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[53] Garcia M, Ruiz V, Godoy A, et al: Differences in polypropylene shrinkage depending on mesh position in an experimental study. American Journal of Surgery Vol 193, Issue 4, April 2007, p538-542.
[54] Aungst MJ, Friedman EB. De novo stress incontinence and pelvic symptoms after transvaginal mesh repair. Am J Obstet Gynecol. 2009 Jul; 201(1):73.e1-7.
[55] Caquant F, Collinet P, Deobodianance P, et al. Safety of transvaginal mesh procedure: retrospective study of 684 patients. J Obstet Gynaecol Res. 2008 Aug; 34(4):449-56.
[56] Argirovic RB, Gudovic AM et al, Transvaginal repair of genital prolapse with polypropylene mesh using tension- free technique. Eur J Obstet Gynecol Reprod Biol. 2010 Nov; 153(1):104-7.
[57] Clave A, Yahi H, Hammou J, et al. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 patients. Int Urogynecol J. 2010 Mar; 21(3):261-70.
[58] Blandon RE, Gebhart JB et al. Complications from vaginally placed mesh in pelvic reconstructive surgery. Int Urogynecol J Pelvic Floor Dysfunct. 2009 Feb 10.
[59] Collinet P, Belot F, Debodinance P et al. Transvaginal mesh technique for pelvic organ prolapse repair: mesh exposure management and risk factors. Int Urogynecol J (2006) 17:315-320.
[60] Abed H, Rahn D, Lowenstein L, et al. Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. Int Urogynecol J. 2011 Jul; 22(7):789-98.
[61] Deffieux X, De Tayrac R, Huel C, et al. Vaginal mesh erosion after transvaginal repair of cystocele using Gynemesh or Gynemesh-Soft in 138 women: a comparative study. Int Urogynecol J Pelvic Floor Dysfunct. 2007 Jan; 18(1):73-9.
[62] Feiner B, Maher C. Vaginal mesh contraction: definition, clinical presentation, and management. Obstet Gynecol. 2010 Feb; 115(2 Pt 1):325-30.
[63] Foon R, Toozs-Hobson P, Latthe P. Adjuvant materials in anterior vaginal wall prolapse surgery: a systematic review of effectiveness and complications. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Dec; 19(12):1697-706.
[64] Krause H, Bennett M, Forwood M. Biomechanical properties of raw meshes used in pelvic floor reconstruction. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Dec;19(12):1677-81
[65] Dietz H, Vancaillie P, Svehla M. Mechanical properties of urogynecologic implant materials. Int Urogynecol J Pelvic Floor Dysfunct. 2003 Oct; 14(4):239-43.
[66] Debodinance P, Engrand J. Development of better tolerated prosthetic materials: applications in gynecological surgery. J Gynecol Obstet Biol Reprod (Paris). 2002 Oct; 31(6):527-40.
[67] Martan A, Svabik K. et al. Incidence and prevalence of complications after urogynecological and reconstructive pelvic floor surgery. Ceska Gynekol. 2007 Dec; 72(6):410-5.
[68] Jia X, Glazener C, Mowatt G, et al. Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systemic review and meta-analysis. BJOG 2008 Oct; 115(11):1350-61.
[69] Falagas M, Velakoulis S, Iavazzo C, et al. Mesh-related infections after pelvic organ prolapse repair surgery. Eur J Obstet

vaginal mesh contraction to demonstrate that the mesh caused the condition. The patients' presenting complaints included severe vaginal pain, dyspareunia, and focal tenderness over contracted portions of mesh on vaginal examination, mesh erosion, vaginal tightness, and vaginal shortening. The patients underwent surgical intervention with mobilization of mesh from underlying tissue, division of fixation arms of the central graft, and excision of contracted mesh. Fifteen of 17 (88%) patients reported a 'substantial reduction in vaginal pain following explantation, while none of 11 (64%) reported 'substantial' reduction in dyspareunia. However, despite Feiner's relative success with mesh explanation, the adverse effects of transvaginal mesh contraction caused permanent life-altering sequelae in 22-46% of patients in this study.

More recently, Letouzey et al. reviewed the long-term changes in pelvic mesh volumes over time using three-dimensional translabial ultrasonography and found mean contraction of 30%, 65%, 85% at follow-up durations of 3, 6, and 8 years, respectively. This study demonstrates that the pathological process that causes mesh shrinkage increases progressive over time and there is a linear correlation of the contraction rate with time, raising the frightening possibility that mesh contraction syndrome continues indefinitely into the future.

A consistently worrisome statistic is that many of the complications related to mesh contraction such as pelvic pain and dyspareunia are delayed in onset. Given the currently reported complication rates, there are a large number of women around the world who have yet to develop problems but given enough time will. In other words, we may be just seeing the tip of the iceberg. Bard's own internal documents indicate a substantial risk of mesh shrinkage of at least 50%.

However, despite Bard's knowledge, neither the original Avaulta Plus or Avaulta Solo IFU nor

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Gynecol Reprod Biol. 2007 Oct; 134(2):147-56.

[70] Froze F, Goldman H. Transvaginal excision of mesh erosion involving the bladder after mesh placement using a prolapse kit - a novel technique. Urology. 2010 Jan; 75(1):203-6.

[71] Diwadkar G, Barber M, Feiner B, et al. Complications and reoperation rates after apical vaginal prolapse surgical repair: a systematic review. Obstet Gynecol. 2009 Feb; 113(2 Pt 1):367-73.

the Surgical Guide adequately warned of the risk of mesh contraction. Nor did Bard conduct any testing to evaluate its synthetic vaginal meshes for shrinkage. [72] Bard also should have known from a 2005 article by Cobb et al that "All *available meshes, regardless of their composition, experience a 20-50% reduction in their initial size. Factors of the mesh itself and the surrounding tissue inflammatory response contribute to this phenomenon.* (emphasis added)"

4. The Pore Size in the polypropylene mesh used in the Avaulta products was inadequate to foster proper tissue in growth.

The Avaulta mesh has inadequate pore size. Bard's internal documents and the testimony of its employees and representatives demonstrate that pore size must be at least 2 mm to provide adequate ingrowth, and to avoid scar plate formation and bridging fibrosis.[73] Instead, the mesh sizes of the Avaulta products, 1.3 mm in the central portion and 1 mm in the arms, have actually been proven to be inadequate to foster appropriate ingrowth by the surrounding tissues. Bard's measurements of the Avaulta mesh pores showed many pore sizes below 1 mm. Some were .649 x .486 mm, and "other pores were not significant enough in size to measure."[74] Rather than allowing the surrounding tissue to integrate into the mesh, the inadequately small pore sizes foster inflammation, chronic foreign body reaction, excessive scarring and a creation of a rigid scar plate. This chronic foreign body reaction and increased inflammation leads to long term complications, including, among others, erosion, chronic pain, nerve entrapment, pain syndromes, sexual dysfunction, chronic dyspareunia, loss of elasticity, mesh contraction, organ dysfunction, voiding dysfunction, muscle and nerve damage, vaginal scarring,

[72] AVAMDL2_00398613; see also AVAMDL2_00448234.
[73] AVA2E0074398 (9/2/08 Mesh Development Proposal memo); AVA2E7593856 (5/21/09 "Current Status of Mesh to BUD Biomaterials Expertise" memo); AVA2E0759628 (11/6/09 "Biomaterials Strategy Overview for Pelvic Health Products" memo); AVA2E0864856 (4/26/11 Bard V.P. for Regulatory and Clinical Affairs Email acknowledging mesh design flaws); (J. Ross depo. pp. 64:23-66:17 (less than 2 mm pore size causes scar bridging and is "not a good thing."); (R. Orr depo., pp. 117:3-13 (published data establishing appropriate pore size of greater than 2 mm was published and available before 2008)); Cobb W et al. "The Argument for Lightweight Polypropylene Mesh in Hernia Repair," Surgical Innovation, Vol. 12, No.1 (March), 2005: pp. 63-69; Klosterhalfen B et al. "The Lightweight and Large Porous Mesh Concept for Hernia Repair," Expert Rev. Med. Devices 2(1), 2005.
[74] AVA20096615 (Mesh Testing Characterization).

the need for multiple surgeries, inability to remove the mesh and irreversible life-long complications.

5. The arms of the Avaulta Solo and Avaulta Plus are unreasonably dense.

The arms of the Avaulta mesh are too dense. The maximum safe weight for such mesh, as Bard admits, is 35 g/m^2[75]. The arms of the Avaulta mesh are nearly two-times as dense at 64.5 g/m^2. Such excess density unreasonably increases the undesirable foreign body reaction to the mesh arms, which, in turn, creates and/or contributes to the creation of a thicker and less flexible scar plate and causes the numerous morbidities listed above and below in this r

6. The design and implantation method causes the mesh to saw the tissues through which the arms are pulled.

The trocar cut channels are not as wide at the mesh and neither are the exit incisions. The channels are also rounded. As a result, when the flat mesh is pulled through those rounded channels, without using a cannula or tube to protect the surrounding tissues, the serrated edges of the mesh at like a saw cutting against adjacent anatomical structures, causing increased inflammatory response, additional pain and invariably greater tissue damage than would occur if the flat mesh were pulled through a flat channel, cut by a flat tipped trocar, that is slightly wider than the mesh arm.[76] This occurs because the rounded trocar holes keep the mesh from lying flat and instead makes them curl, roll and/or fold. When curled, rolled and/or folded, the pore size, noted as too small above, becomes even smaller,

[75] AVA2E0074398 (9/2/08 Mesh Development Proposal memo), p. 4399 ("the mesh should be less than 35 g/m^2."); *See also*, AVA2E0864856 (4/26/11 Bard V.P. for Regulatory and Clinical Affairs Email acknowledging mesh weight should be less than 35 g/m^2); AVA20020365 (Bard internal measurements for density of Avaulta Plus mesh arms);

[76] AVA2E0996849; AVA2E0116770; AVA2E0218343 (7/20/06 Bard Email stating "[doctors] *see tearing the arm through the tissue...as a major disadvantage* [of the Avaulta product].*We would need data to say that it does not cause injury to the tissue* [as compared with the arms on a competing device, which were covered by a protective sheath during insertion] *if we were going to say that protecting that tissue from the arms was not important*."); AVA2E1439452 (10/10/07 Bard Email addressing doctor's "arm sawing" concerns, stating doctor "*is not alone in his concerns*" and that "*[t]he onus is on us to prove that the passing of naked mesh arms does not cause any harm.*"); AVA2E0225785(10/7/08 Bard internal memo recognizing need to "Reduce/eliminate sawing action of arms on pull through"); AVA2E5506346 (March 30, 2009 Bard internal memo discussing presentation by Bard expert, Vincent Lucente, that doctors "should never use a kit that did not have some form of sheathing/canular system for passing the arms…because of the sawing of tissue you would be doing pulling the mesh through and around the fulcrum, and that it could lead to increased pain, and poor outcomes.").

which again contributes to the lack of proper tissue ingrowth, increased scarification, contraction of the arms, and the other adverse outcomes noted throughout this report.

7. The blind passage of the trocars to implant the Avualta products is unsafe

Another unreasonably dangerous design flaw is the requirement that the surgeon cut channels with the trocar needles through a blind passage where the surgeon cannot see where the trocar is cutting and what it has cut. This technique is the "blind" passage previously mentioned. It creates an inherently, unreasonably dangerous risk of causing perforated and/or lacerated organs and excessive damage to nerves, vascular structures and other tissues.[77] Safer designs that do not depend on the surgeon using the blind passage of the trocars would eliminate, if not reduce, this unnecessary risk.

8. The asymmetric pull of the arms makes the Avualta products unsafe

Whenever excessive scar plating occurs on the previously noted high density, overly small pore, roped, curled, folded and otherwise, deformed mesh arms, they shrink and pull unevenly on the central portion of the mesh. This occurs because the placement of the mesh and the arms, as well as the amount of scar tissue that develops, is never completely symmetric from one arm, across the central mesh portion, to the other arm. This asymmetry is due to the different amounts of curling, roping and other deformations that occur on each arm during surgery and post-operative scarring tissue in growth.

This uneven stretching, pulling and tightening across the arms and the central portion of the mesh causes, and increase the potential for, the mesh to erode or extrude. These scar formations also pull inwardly and unevenly on the anchoring points in the pelvic sidewall muscles (obturator and levatorani), forcing these anchoring points and the muscles to which the arms are attached out of their

[77] AVA2E0114456 (March 2, 2009 Bard Product Opportunity Appraisal Form) ("The market for pelvic floor grafting systems is changing. New technologies have focused on minimizing the number of incisions required for implantation resulting in a better patient experience, ostensibly better pain scale results and lower ambulation times. Furthermore, these 'single incision' technologies do not require the passage of trocars/needles potentially reducing the amount of tissue damage and the potential for laceration of adjacent neurological vascular structures.").

normal positions and asymmetrically toward the midline, while simultaneously pulling the central portion of the mesh asymmetrically away from the midline.

This uneven pulling on the pelvic sidewall muscles causes pain even when the woman is at rest but can also be particularly acute during sexual intercourse and defecation. Even attempts at defecation or sexual penetration act upon the mesh and increase the strain upon the arms, which in turn causes new or worsening pain. Also, during coughing, jumping, or straining, and other activities of normal daily living uneven pressure is placed on the mesh, which in turn is unevenly transmitted to the attachments in the pelvic sidewall, further deforming and pulling on the muscles and the central mesh portion.

9. Avaulta Plus' porcine collagen causes an even greater inflammatory response than the synthetic polypropylene mesh alone.

Rather than reduce the inflammatory response, the porcine collagen sheet that Bard attached to the Avaulta Plus mesh causes an even greater inflammatory response than that shown for the polypropylene mesh previously in this report. This heightened inflammatory response increases the number of macrophages, foreign body giant cells and other inflammatory cells. The heightened number of inflammatory cells can cause discharge, bleeding, delayed healing, erosion, extrusion and ultimately even rejection of the mesh. Bard's own internal documents[78] recognize that the collagen element of the Avaulta Plus graft is the primary cause of persistent delayed healing, just as they saw with their Pelvicol and Pelvisoft, two of their other collagen products in the early 2000s, several years before they marketed Avaulta Plus.

10. Because of their Transvaginal implantation method, Avaulta Plus and Avaulta Solo have an abnormally high risk of adversely contaminating the surgical field with bacteria and other microbiotics.

[78] See e.g. AVA2E0094647; AVA2E0094910; AVA2E0880430; AVA2E0799229-30 (Bard email from A. Bowyer to Dr. Krick ("With the Avaulta Plus there is a higher risk of delayed healing/extrusion/rejection etc because of the porcine.")); AVA2E1131047-50 (Bard email from Jon Conta to Dr. Bailey ("Very glad to hear you're not seeing any exposures with the Solo. Your experience mimics others, and continues to confirm to us that the delayed healing is specific to the collagen on the Plus….")); AVA2E0072438 (7/25/06 Emory rat study demonstrating chronic inflammatory response, encapsulation, and minimal tissue ingrowth with porcine collagen patch).

The transvaginal method for implantation of the Avaulta Plus and Avaulta Solo require the products to be implanted from outside the vagina to inside and behind it. It is not disputed in the medical field that the vagina is a "clean-contaminated" space. This means that even after intensive sterilization of the mesh product and the trocars, the normally prevalent vaginal flora attach themselves to the mesh and the trocars, which drags the vagina's flora into the operating field and contaminating it. The operating field cannot be cleansed of the contaminants brought into it by the trocars and the mesh itself from the vagina.

The normal vaginal flora includes a diverse array of bacteria, from Lactobacillus, gardnerella, E. coli, Staphylococcus, to Acinterobacter and Candida species, among many, many others. Since due to the transvaginal approach these bacteria necessarily attach themselves to the trocars and the mesh, they are necessarily also implanted alongside the mesh and colonize the surgical field. The presence of this bacteria inside the body can cause abscesses, fistulae, and infection, especially due to the Lactobacillus, the most common of the vaginal bacterial flora. Further the porcine collagen sheet affixed to the Avaulta Plus allows for greater bacterial attachment as there is more surface area to which the bacteria can stick, increasing the opportunity still further for abscesses, fistulae, and infections.

There have been several studies showing significant bacterial colonization and infection of polypropylene mesh in the operating field. In 2008, Boulanger, et.al. reported results of a bacteriological analysis of meshes removed for complications after stress incontinence and prolapse surgery, 62% of which were removed for erosion. Cultures were performed. To some degree bacterial contamination was found in every sample removed and tested. Similarly, in 2009, Vollebregt, et. al. published results from a study where they took culture swabs of core mesh taken during surgical implantation of vaginal mesh. 67 implants were cultured and 56 (83.6%) of the implants were positive for vaginal bacteria. They concluded that "colonization of vaginally implanted mesh occurs frequently."

As late as 2012, Shah and Badlani found mesh infections in mesh patients. They described the clinical presentation of the patients whose mesh was infected to have included:

- Nonspecific pelvic pain;
- Persistent vaginal discharge or bleeding;
- Dyspareunia;
- Urinary and/or fecal incontinence;
- Induration of vaginal incision;
- Vaginal granulation;
- Draining sinus tracts; and/or
- Graft erosion.

Moreover, certain species of the most common bacteria, the Lactobacillus, found in the clean contaminated environment of the vagina are known producers of hydrogen peroxide, which as described above, is known to degrade and embrittle Bard's Marlex polypropylene mesh from which the Avaulta Solo and Avaulta Plus are made. Thus, the entire approach of transvaginal implantation raises much greater risks of infection than traditional non transvaginal approaches.

11. Despite knowledge that removal of the mesh may be necessary under certain circumstances, Bard never developed a way to remove the mesh after it was implanted.

Should removal of the mesh become necessary, there is no way to remove it safely once it is implanted and scarified and subject to tissue ingrowth. The scars, especially those around the arms, surround the mesh so completely that it is virtually impossible to excise it at all. Despite knowledge of these many complications caused by the mesh, Bard never even considered how to remove the mesh after implantation, whether in whole or in part. In fact, an internal Bard PowerPoint recognizes that one

of the "weaknesses" with its pelvic organ prolapse kits is "[t]repidation surrounding removal of kit system should something go wrong long-term."

The inability to remove all of the mesh can condemn a woman to irremediable, lifelong complications, of the kind noted previously in this report. Unfortunately even removal of all or some of the mesh, where practical, can increase the presence of scar tissue which can itself increase chronic and permanent pain, among other complications. In other words, the excision of the mesh may leave the woman in worse pain.

12. Safer alternative designs to the Avaulta Solo and Avaulta Plus were available when Bard began marketing them.

There are several alternatives to the design of the Avaulta Plus and Avaulta Solo products that are safer and just as effective. For instance, in 2002, Bard (through its employees, Doug Evans and Kenneth Butcher) applied for a patent for a "Natural Tissue Self-Anchoring Sling and Introducer System" using natural tissue instead of the synthetic polypropylene. In this patent application, Bard referred to the synthetic mesh material then in use as treatment for stress urinary incontinence (polypropylene), and explained that the mesh:

> "*[I]s subject to a higher risk of causing erosion of the patient's tissue than are natural materials. Furthermore, the synthetic mesh material has a higher risk of infection than does natural material, probably because the mesh provokes a foreign body reaction from the patient's body. The synthetic material also tends to have a greater amount of scar tissue formation around the mesh fibers, instead of vascular ingrowth.*" [79]

An abundant amount of medical literature and basic science data over the past 40 years indicates the strong and direct relationship between postoperative complications and mesh design.[80] Reducing

[79] AVA2E6681921.

[80] Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia (1997) 1:15-21; Bouikerrou M, Boulanger L, Rubod C et al: Study of the biomechanical properties of synthetic implanted in vivo. European J. Obstet & Gynecol and Repro Bio 134: (2007) 262-267; Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg. 1999 Jul; 165(7):665-73; Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. J. Surgical Research 103, 208-214 (2002); Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. European Journal of Surgery Volume 164, Issue 12, pages 965–969, December 1998;

mesh-related complications demands a thorough understanding and knowledge of the chemical, physical and synthetic characteristics of meshes and how they react inside the human body. Based upon vast amounts of general surgery and basic science literature, there is a consensus that synthetic meshes that are lighter weight, larger pore size, monofilament, and that are capable of maintaining their elasticity and structural stability will have better results with fewer complications. Of all the mesh characteristics mesh porosity, mesh pore size and mesh stability under load are the most important. If a mesh product's design does not allow for effective tissue integration and fibrotic bridging occurs instead, leading to a rigid scar plate, many adverse events can occur such as erosion, nerve entrapment, pain syndromes, dyspareunia, loss of elasticity, mesh contraction, organ dysfunction and the need for reoperation.

White et al. published an article suggesting that inflammatory response may also be explained by the amount of movement of the implant and mechanical stresses that are placed on the mesh. As the movement and mechanical stresses of the pelvic floor differ extensively to that of the abdominal wall, it should have been obvious to Bard that the inflammatory response would not only be different, but also more intense in a pelvic floor implant.

In the late 1990's, studies were published by Klinge et al. in which explanted hernia mesh was analyzed from rats, dogs and humans. They discovered that in some patients, a chronic foreign body reaction could still be observed after 15 years. Given that this implant is meant to be placed permanently in a woman's pelvic tissue, to base the safety and efficacy of Avaulta Plus and Avaulta Solo on studies that were short-term (6 months or less in duration), while studies were available in the scientific literature showing potential complications up to 15 years, was irresponsible. Generally speaking, the

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Klosterhalfen B, Klinge W, Schumpelick V: Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair. Biomaterials. 1998 Dec; 19(24):2235-46; Klosterhalfen B, Klinge W, Hermanns B et al: Pathology of traditional surgical nets for hernia repair after long- term implantation in humans. [ABSTRACT] Chirugr 2000; 71:43-51; Krause H, Galloway S, Khoo S et al: Biocompatible properties of surgical mesh using an animal model. Aust N Z J Obstet Gynaecol. 2006 Feb; 46(1):42-5; Garcia M, Ruiz V, Godoy A, et al: Differences in polypropylene shrinkage depending on mesh position in an experimental study. American Journal of Surgery Vol 193, Issue 4, April 2007, p538-542; Cappelletti M, Attolini G, Cangioni G, et al. The use of mesh in abdominal wall defects. Minerva Chir. 1997 Oct; 52(10):1169-76.

women who undergo these POP mesh procedures are between 30 and 60 years of age. To have a chronic foreign body reaction that can continue for an unmeasured amount of time in a woman who will have this mesh implanted for decades is unsafe and can potentially lead to life-long debilitating pain and complications. Studies that have analyzed the complications that occur years after implantation, such as those performed by Klinge and his colleagues, should have provided Bard with a more comprehensive understanding of the true long-term risks and complications to patients, and at the very least, should have prompted Bard to conduct long-term controlled studies prior to any marketing of the Avaulta systems. The internal Bard documents and depositions are filled with references to the chronic foreign body reaction and inflammatory response by the body to the mesh.[81] Despite this knowledge, Bard chose to market the low pore size, heavy weight mesh in the Avaulta Solo and Plus.

13. The design of the Avaulta Solo and Avaulta Plus with four arms and blind trocar implantation method is inherently flawed.

As discussed above, Bard's implantation method is inherently flawed in the Avaulta Plus and Solo products. There are safer implantation designs available, including abdominal sacrocolpopexy (ASC) and single incision/non-trocar based implantation. The ASC is designed to make the full length of a woman's vagina available for sexual intercourse. Contrary wise, the transvaginal method typically results in shortening of the vagina. Also, implants used in abdominal sacrocolpopexy are passed into position via an abdominal incision, and are not exposed to the native bacteria of a woman's "clean contaminated" vagina. This reduces the potential for vaginal flora to colonize the surgical field, with the concomitant risks already discussed in this report. The elimination of blind trocar passage also reduces numerous risks associated with the Avaulta Plus and Solo products, and represents a safer feasible

[81] For instance, the porcine collagen sheet affixed to the Avaulta Plus mesh causes a greater inflammatory response. See also, AVAMDL2_00398613 (contains pictures of polypropylene inguinal hernia mesh explants with these captions: (1)"extensive fibrotic scar"; (2) "polypropylene devices contracted and migrated"; (3) "folds in mesh: contraction, shrinkage"; and (4) "polypropylene device encapsulated and shrunken..; AVA2E0074398; AVA2E0087168

alternative product design. Moreover, implants used as reinforcement in abdominal sacrocolpopexy are anchored in a vertical direction, and are not attached to the muscles in the pelvis. As a result, when the contractions associated with normal healing during actually lengthen the vagina. Products designed for abdominal sacrocolpopexy implantation are safer, feasible alternatives to transvaginal mesh, such as Avaulta Plus and Avaulta Solo mesh products.

Bard has products, such as the Alyte, implanted by way of Sacrocolpopexy, and the Nuvia SI, implanted via a single incision, which require none of the four arms of the Avaulta Plus and Solo and which eliminate many of the risks of the blind passage and the contamination of the surgical field.

14. Bard had no long-term pre- or post-market testing conducted to determine the risk of long-term complications women would encounter with the Avaulta Solo and Avaulta Plus.

Bard never did any basic research to determine the safety and efficacy of how the mesh will perform after implantation. Instead, it consistently refused to conduct such research, even after receiving the pleas of one of its leading consultants. Whether to determine the pressures on the pelvic floor or to study the incidence of adverse reactions or otherwise, Bard time and again refused to perform any pre- or post-marketing testing.

For example, Claire Gloeckner in her October 17, 2008 email, , acknowledged that she never got it off of her "to do" list. This was more than a year after Bard begun marketing and selling the Avaulta Plus. She and Bard's Chuck Thomas traded emails about pressure in the pelvic floor.[82] Understanding those forces and pressures is essential to designing a product that was over engineered for pelvic floor repair, where the stresses and strains of normal daily activities differ so greatly from the hernia surgery site, for which the mesh was originally made.

Moreover, Bard never sought to perform any institutional review board (IRB) approved randomized controlled trials, anywhere, in the United States, or overseas,to determine safety and

[82] AVA2E8019849

efficacy before selling these products. Dr. Ross, one of Bard's leading consultants, proposed a protocol to assess the safety and effective of Avaulta Plus, seeking to gather t additional data to validate the long-term safety and effectiveness between investigational sites. Instead, in the face of Dr. Ross' proposed clinical study, Bard stopped any activity on it as it was deemed to be not cost effective. Indeed, neither Bard nor Sofradim, whose product Bard purchased, included any clinical data in their 510k submission.

Bard even recognized that it was in its own self-interest to profit by the having done a long term, RCT, as it would or could give support to its sales representatives in the field. Sales reps and doctors were complaining that the lack of long term RCT was hindering sales. Tellingly, in response to an email requestseeking clinical papers showing 1 to 2 year follow-up, Bard did not even offer up the one year data from deTayrac, possibly because by that time Bard was knew of the 3 year data by de Tayrac reflecting an erosion rate increase from 6.3% to 14% (AVA2E0063853-3) and the de novo dyspareunia rate of 18.5%. (AVA2E0375064). Clearly the release of what data it had would have hurt sales and not helped them.

Finally, the FDA on January 3, 2012, 522 Ordered Bard to perform post-market surveillance studies on the Avaulta Plus, Avaulta Solo, PelviSoft and Ajust products. (DeFord exhibit 17) Following discussions Bard had with the FDA regarding the 522 Order, Bard was told that it must conduct the requested post-market surveillance study on the Avaulta products, or stop selling the products in the United States. (DeFord exhibit 18) By month's end, instead of agreeing to perform the RCT required by the FDA, on January 31, 2012, Bard told the FDA in a letter that it intended to withdraw the Avaulta products from the market and did not believe a post-market surveillance study was needed. Dr. DeFord testified that Bard's choice to pull the product from the market was based on declining sales of the Avaulta products and an lack of ability to get the Nuvia (a next generation product) cleared in the US market "down to a point where financially it didn't make any sense to

continue on." (2/15/2013 DeFord deposition, p. 191) Ironically, Dr. DeFord then agreed that one of the factors that caused the drop in Avaulta sales in the first place was a lack of clinical studies on the products. (2/15/2013 DeFord deposition, p. 192) Even more ironically, had Bard continued with Dr. Ross's proposed study, that data would likely have been available and possibly published before Bard ever received the 522 Order in 2012. The main expedient for Bard is and was sales. As Dr. DeFord put it so succinctly, "So, you know, *if the sales were a billion dollars, it's different than if sales are $3 million*." (emphasis added) (DeFord Deposition, p. 212-213) Without a long term RCT or the FDA mandated pot-marketing surveillance study, the only population that exists today from which any data can be collected today is the "test" population of women who had the Avaulta products implanted in them.

In sum, safety and efficacy of using a non-inert implant material in the presence of compounds that break it down should have been determined before marketing. Such RCTs could also have helped develop methods for doctors to resolve the numerous complications above, perhaps even determined best surgical practices for removing the mesh should it become necessary to do so.

15. Bard's animal testing was insufficient and not correlated to prove the safety and effectiveness of the Avaulta Solo and Avaulta Plus in humans.

Bard performed the most minimal animal testing of the Avaulta mesh that it could. It inserted the mesh into the abdominal wall of rats and rabbits and four sheep vaginas.. These studies could not be extrapolated to humans for several reasons. Fist, humans and sheep are no functionally alike. Second, trocars were not used in this study. Third, the mesh did not have arms, so consequently none of the heavy weight mesh that comprises the arms of the Avaulta mesh systems were implanted and tested. Fourth, among others, the period of time allotted, 45 days, is not of a sufficient duration to make a reasonable assessment for a permanently implanted device. In consequence, it is impossible to evaluate critical features of the system, its use in actual surgery, or its behavior with animals let alone human

beings, which Bard nevertheless did evaluate favorably for itself. However, even the Bard employee who wrote many of the studies, in her deposition, testified that she did not conclude that the Avaulta Plus hybrid graft could be safely used in women. (Mercuri Deposition, pp. 214-215)

16. The deleterious effect of collagen material on would healing was known to Bard.

Bard knew that collagen's use was associated uniquely with delayed wound healing complications[83]. Wound dehiscence is not something typically seen with traditional native tissue repairs, even though Dr. Ross authored a paper entitled "Persistent Delayed Healing: Causes, Preventive Measures, and Conservative Treatment." And stated, "[b]y increasing the inflammatory response at the suture line, we believe the collagen element of the Avaulta Plus graft is the primary cause of PDH, as this is consistent with PDH seen previously in our Pelvicol and Pelvisoft products." [84] (AVA2E0094647). Moreover, Bard did not even disclose these facts to its Senior Vice President for Science, Technology and Clinical Affairs, Dr. DeFord. (2/14/2013 DeFord Deposition at pp. 73-75). Bard did not release this information to doctors or the FDA.

17. Bard knew of the h worsening safety of mixingpolypropylene and porcine collagen

With only a hope that a combination product would prevent erosions, Bard created a product that had layers of polypropylene combined with porcine collagen dermis despite their knowledge of known problems with both materials in a woman's pelvis. However, Bard had no scientific foundation to make such an assumption. In fact, Bard had ample reason to know that the opposite was likely more true than not. A study where the materials were implanted into sheep,[85] found "a prolonged inflammatory response from the Hybrid material consistent with the normal healing process, while Avaulta showed no/very minimal signs of inflammation. The inflammatory cells were apparent more around the porcine

[83] AVA2E0094910 (document stating since 2004, 19 complaints have been received by Bard).
[84] It is worth noting, clinical evidence in Bard's possession indicates in one study of Pelvicol, a collagen product, PDH was noted in 42% of patients implanted without hydrodissection and 11% for patients implanted using the hydrodissection technique. (AVA2E0880430)
[85] The "hybrid" product in this study was ultimately marketed and sold in the United States as the Avaulta Plus.

dermis than around the PP mesh in the Hybrid implants, which is to be expected. This could be a host response to the structure or composition of the porcine material." (AVA2E0066011) Concluding, "[t]he anatomical location of the implant provided data that could not be obtained from other sources. This study merely showed data with regard to implantation and histologic outcome, duration of implant of the materials are more appropriately assessed over a longer duration in vivo. " (AVA2E0066011). Bard never tested the implants with a longer duration.

Dr. Ciavarella, Director of Clinical Affairscritiqued Jennifer Mercuri's "sheep report"and raised highly critical questions concerning the validity of her findings which questions Bard conveniently ignored in the final report. Examples of the questions and issues raised include (Dr. Ciavarella's editorial remarks are in italics):

> Re: a marketing claim: "Promotes tissue integration, remodeling, vascularization, and cellular infiltration. *Promotes? Or does all this happen despite the presence of the mesh?"*

> Re: histologic findings: "no adverse events were detected (macro- and microscopically) in the vaginal mucosa when compared to a 'non-protected' mesh. *It looked like a lot of scar tissue between the collagen and mesh."*

> Re: inflammatory reaction: "Given that the primary cells in these inflamed regions were lymphocytes and not other known cells of chronic inflammation, the reactions should not warrant a cause for major concern ...*I don't understand this sentence. What other 'known cells of chronic inflammation' are being referred to*?"

> Re: reaction to porcine: "It has been shown in previous studies that porcine tissue evokes a host tissue inflammatory reaction ...*I was surprised at the extent of the reaction. Were there prior studies of Collamend or similar materials that show the same thing?"*

> Re: the length of the inflammatory response: "While the presence of inflammatory cells at 45 days would indicate a prolonged inflammatory response, it is plausible that the response would diminish over time. *It is also plausible that it would persist long enough to be clinically significant."* (AVA2E0072787).

Additionally, if a collagen material derived from pig dermis is sewn to a polypropylene sheet, the Collagen sheet will further inhibit the tissue integration with minimal mesh contraction. Thus, while the

collagen sheet does contain some perforations, those perforations were infrequent in number and location. As Dr. Ross describes:

> Think for a moment about the surface area of an Avaulta Plus graft vs. an Avaulta Solo or other purely synthetic mesh graft. The meshes themselves have very little surface area – they're mostly 'holes' or open space in between polypropylene fibers. The Avaulta Plus graft has a piece of collagen covering that mesh; though that too has holes, it is predominantly collagen, not open space. Thus the Avaulta Plus graft has substantially higher surface area and greater overall mass than does purely synthetic mesh…Its increased mass, thickness, and stiffness as a result of the collagen may also contribute to the patient's reaction to the implant." (AVA2E0094647)

Initially, at marketing, the the Avaulta Plus, was the first trans-vaginal mesh that surgeons had available to them which had a porcine collagen sheet attached to polypropylene. Since this was the case, Bard should have warned surgeons there were studies supporting the safety or efficacy of the combined materials for implantation transvaginally. Bard should have also told surgeons of the effects that the collagen sheet would have on tissue integration, effective pore size, scarring, fibrosis, potential reactions, and scar plate formation. Instead, Bard gambled on a known losing hand that attaching a known problematic porcine skin to the polypropylene would solve a problem rather than commonsensically compounding it.

18. Despite knowledge about complications associated with their products, Bard never developed or communicated a contingency plan for managing them after the devices were implanted.

Bard knew of problems with erosion, infection, scarification, and other life altering problems that their products and the method of implantation for these products could create. Yet, Bard prepared no documents, or reports advising doctors on how to treat these complications should they occur. One of the most significant complications is "pain." However, that significant complication is absent from Bard's 02/07 IFU section Adverse Reaction." (AVA20164147). In fact, severe and unrelenting pain following mesh surgery is common plance and presents a problem for patients. While post-operative pain can occur with traditional prolapse surgery, however, pain which alters the life of a patient after the

procedure has rarely occurred. But, pain resulting from the mesh arm placement by trocar can alter a woman's life permanently. However, neither Bard nor Sephardim investigated how to resolve such a complication before marketing these products. Dr. David Ciavarella stated that he understood from speaking with surgeons that it was hard to extract the mesh once scar tissue encapsulated it. (9/4/2012 Ciavarella Deposition, p. 43.) Dr. Ciavarella also testified that the did not know if Bard performed any research to determine if surgeons would encounter the same difficulties encountered when removing hernia mesh and when they try to remove polypropylene mesh from the pelvic floor. (9/4/2012 Ciavarella Deposition, p. 44) For informed consent to be a valid process, a patient must understand that she might suffer a traumatic course if the permanent device fails . Yet, Bard never determined how to safely remove the mesh and never instructed doctors on the science of removal and the complications arising from it.

VII. BARD FAILED TO DISCLOSE PERTINENT ADVERSE RISK INFORMATION, PERTINENT INFORMATION ABOUT THE DEFECTS IN THE PROPERTIES OF THE MESH AND THE FAULTY SYSTEM OF IMPLANTATION REGARDING THE AVAULTA PRODUCTS TO PHYSICIANS AND THEIR PATIENTS.

As discussed throughout this report, Bard failed to disclose pertinent information regarding adverse risks, defects in the properties of the mesh and the inadequacies related to the way the Avaulta was to be implanted. Bard also failed to disclose to physicians and patients the numerous, serious, life-altering consequences of surgery using the Avaulta Solo and Avaulta Plus systems. In addition, Bard failed to disclose to physicians or their patients the severity, frequence, duration and irreversibility of the all the complications associated with its Avaulta products.

Specifically, Bard's Instructions for Use ("IFU") fails to disclose important safety and risk information to physicians thereby compromising the ability for all level of surgeons to adequately and appropriately consent their patients prior to the implantation of the Avaulta device. Although there are other sources of information, the IFU is the one document that all surgeons see prior to the implantation

of the Avaulta device. I have personally used numerous IFUs to gain risk information regarding medical devices and drugs. I routinely use IFUs (and DFUs) in my practice. Myself and other physicians rely on device manufacturers to give us all of the risk information they know related to a device as I am expected to be the expert on the pelvic floor with respect to risk information and to discuss risk information with patients in an appropriate risk/benefit informed consent discussion. As such, all risks associated with a medical device must be included in the products' IFU. (Barry, 11/30/2012, 303:4-304:5; Cavagnaro, 8/20/12, 92:25-93:8; Barry, 308:8-20). This is crucial so that all physicians know the safety and risks information known to a company related to a specific product so that an appropriate risk benefit discussion can take place.

Bard failed to warn that the implantation of Solo and Plus were permanent. In addition, Bard failed to warn that the complications from the Avualta device may require additional surgeries that may or may not resolve them. Bard failed to warn doctors that explanation of the mesh, if necessary, would be difficult or impossible to achieve and that few surgeons are qualified to even attempt it. Bard failed to warn that severe and/or de novo chronic sexual dysfunction and dyspareunia may result after implantation of the Avaulta device. Bard failed to warn that patients had the potential to lose all ability to engage in sexual intercourse as result of receiving the Avaulta products.

Bard failed to warn that the Solo and Plus systems would increase the likelihood of erosions. Bard failed to warn, particularly with the Plus system, that Persistent Delay in Healing may occur. Bard failed to warn that the pore size of the mesh was too small to permit proper tissue ingrowth. Bard failed to warn that the effective pore size was too small to permit proper tissue ingrowth. Bard failed to warn that the asymmetrical scarring and contracture of the arms, and the resulting unequal pulling on the central mesh by the arms, would result in chronic pain, even when a woman is at rest, but also during her performance of the usual activities of daily living, such as coughing, straining, sneezing, straining,

etc. Bard failed to warn that scarring in general would result in chronic pain. Bard failed to warn that nerve entrapment could occur as the mesh contracts resulting in chronic pain. Bard failed to warn that the Avaulta Solo and Plus mesh were made from non-medical grade polypropylene. Bard failed to warn that implanted mesh is not inert. Bard failed to warn that mesh degrades in the body, particularly in the presence of oxygen and peroxides and in women with a vaginal pH greater than 5.0. Bard failed to warn that the transvaginal method of implanting Avaulta Solo and Plus through the "clean contaminated" vagina would entrap bacteria and other microbiologics in the mesh contaminating the operating field, resulting in degradation of the mesh, fistulas, adhesions, infections, and other adverse results, leading to erosion and delayed wound healing. Bard failed to warn that the entrapment of certain microbiologics would result in the degrading of the mesh and the release of toxic compounds. Bard failed to warn that such contamination is virtually impossible to prevent, avoid or remedy.

Bard failed to warn that the risk of erosion of synthetic polypropylene is greater than for natural materials. Bard failed to warn that the risk of infection from synthetic polypropylene is greater than for natural materials. Bard failed to warn that the risk of scarification from synthetic polypropylene is greater than for natural materials. Bard failed to warn that the risk of complications generally from synthetic polypropylene is greater than for natural materials. Bard failed to warn that the degradation of the mesh could result in the "fishing line" effect, where strands of the polypropylene slice through adjacent tissues deleteriously. Bard failed to warn of the "barbed wire" effect, whereby damaged and degraded mesh, whose damage lead to more infection moves through the implantation area through activities of daily living. Bard failed to warn of the "sawing" effect on adjacent tissues when the flat mesh arms are pulled through the round trocar holes without a sheath or cannula surrounding the arms. Bard failed to warn that the flat mesh will curl, rope, twist, fold and otherwise deform when pulled through the rounded channels made by the trocars which were narrower than the mesh arms themselves.

Bard failed to warn that the curling, roping, twisting and folder, would effectively further reduce the already too small pore size. Bard failed to warn that it had no clinical data supporting the long term safety and efficacy of the Avaulta Solo and Plus systems. Bard failed to warn that its animal studies did not support the long term safety and efficacy of the Avaulta Solo and Plus systems. Bard failed to warn that its animal studies did not correlate to the procedures for implanting the Avaulta Solo and Plus in women. Bard failed to warn that the asymmetrical pull of its arms from shrinkage would result in chronic pain, even when a women is at rest but also during her normal activities of daily living, including by not limited to sneezing, coughing, straining, defecating, lifting and walking, among many others. Bard failed to warn that the density of the arms was nearly twice the maximum density that Bard had determined was appropriate for implantable mesh. Bard failed to warn that the design of more lightweight, open pore meshes is needed to avoid or minimize adverse effects such as dyspareunia, chronic pain, erosion, extrusion, dehiscence and abscesses, and their recurrence. Bard failed to warn that their meshes were over engineered with regard to the strength needed for pelvic floor functionality. Bard failed to warn that their meshes have a shrinkage rate of 30 to 50% which was directly linked to scar plate formation that does not integrate with the surrounding tissues over time. Bard failed to warn that scarification significantly increases tension on the mesh by shrinking the tissue around the mesh. Bard failed to warn that contractions of the mesh and/or tissues can cause deformation of the mesh such as foldings, curling, bunching and which can cause temporary or chronic pain and facilitate further scar plate formation and the entrapment of nerves, resulting in still more temporary or chronic pain. Bard failed to warn that the “blind passage” of the trocars and the mesh created an unreasonably larger risk of damage to pelvic floor tissue, including but not limited to nerve damage, organ perforation and tissue trauma, especially when compared to traditional repairs such as sacropolpopexy. Bard failed to warn about the rates of complications as they became known to it. Absent these warnings and the other

warnings discussed in this report, the physicians could not explain fully to their patients the risks, safety and efficacy of the Avaulta Solo and Plus systems and thereby obtain from their patients their fully informed consent to undergo those procedures. Based on the information known to or reasonably determinable by Bard, Bard's representation that the risks associated with Avaulta Solo and Plus are the same as any other implantable material (necessarily including native tissue repairs) is unreasonably and recklessly inaccurate and misleading.

VIII. AS A RESULT OF DEFECTS IN THE DESIGN OF THE AVAULTA SOLO AND AVAULTA PLUS, PLAINTIFFS SUFFERED AND CONTINUE TO SUFFER INJURIES.

The defective design of the Avaulta Solo and Avaulta Plus, as well as the failures to disclose pertinent risk and product information to physicians and patients, caused, contributed to the causation of, and/or increased the risk of causing the numerous serious and potentially permanent morbidities, adverse events and complications discussed in this report. For instance and without limiting the foregoing of this report, synthetic transvaginal meshes for POP, including the Avaulta Plus and Avaulta Solo, subject patients to needless danger through increased risks not present in traditional, non- mesh surgery for POP repair, including but not limited to pain associated with the implant procedure (including but not limited to nerve, vascular, organ and tissue damage), chronic pelvic pain associated with fibrosis and scarring, adhesions, chronic vaginal pain, vaginal retraction and shortening, fistula formation, granuloma formation, chronic infection associated with, among other things, the product's implantation into a clean/contaminated field and the chronic, intense inflammatory response to the polypropylene, chronic wound healing issues, organ erosion, vaginal extrusion/exposure, chronic pelvic and vaginal pain associated with the explant procedure (including but not limited to nerve, vascular, organ and tissue damage) , de novo and recurrent incontinence, and de novo and/or recurrent and/or increased significant dyspareunia (painful intercourse), sexual dysfunction, excessive scar formation (contributively causing pain, dihiscense, abscess, erosion and extrusion), chronic infection, vaginal shortening, vaginal

narrowing, vaginal fibrosis, loss of elasticity, mesh contraction, organ dysfunction, muscle and nerve damage, pelvic myalgia, the need for reoperation, discharge, bleeding, delayed healing, and ultimately even rejection of the mesh.

Moreover, patients implanted with non-absorbable, transvaginal synthetic mesh for pelvic organ prolapse, including Avaulta Plus and Avaulta Solo, do not have demonstrable improvement in symptomatic results over traditional, non-mesh repair, have demonstrably worse improvement in their quality of life (QOL) over traditional, non-mesh repair and do not have demonstrable improvement in reoperation rates over traditional, non-mesh repair. Even when surgeons used the Avaulta Plus and Avaulta Solo as designed and marketed, they were unsafe for patients through their intended use as methods of surgical POP repair because of patient-to-patient anatomic variability and surgeon-to-surgeon variability in experience, training and technique.

Simply put, there was no need for the Avaulta Plus and Avaua Solo, non-absorbable, synthetic mesh, to be sold and marketed as a surgical treatment and procedure for pelvic organ prolapse (POP) as there were safe, effective and reasonable alternative surgical treatments available at the time this product was launched that did not needlessly endanger patients nor carry the likelihood or risk of serious injury that has been associated with the Avaulta Plus and Avaulta Solo. Accordingly, the Avaulta Plus and Avaulta Solo should have never been marketed to surgeons or patients in the first place, and I agree with Bard's decision to cease marketing the Avaulta Plus and Avaulta Solo for use in the United States.

Because of its actions, Bard exposed patients to, and/or increased their likelihood to suffer needless, preventable danger, harm and permanent injury and suffering. Importantly, Bard's failure to disclose risks known to it about the Bard to physicians took away their ability to properly and appropriately consent their patients.

EXHIBIT 1

Curriculum Vitae and Bibliography
Daniel S. Elliott, MD

Present Academic Rank and Position

Consultant - Department of Urology, Mayo Clinic, Rochester, Minnesota	07/2003 - Present
Associate Professor of Urology - Mayo Clinic College of Medicine	01/2013 - Present

Education

Biola University - BS, Biological Science	1988
School of Medicine, Loma Linda University - MD	1993
Mayo School of Graduate Medical Education, Mayo Clinic College of Medicine - Internship, General Surgery	1993 - 1994
Mayo School of Graduate Medical Education, Mayo Clinic College of Medicine - Resident, Urologic Surgery	1994 - 1999
Baylor College of Medicine - Fellow, Neurourology, Urodynamics and Voiding Dysfunction	1999 - 2000

Additional Education

UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2004
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2005
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2006
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2007
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2008
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2009
Coloplast Surgical Training - Male Sling New York, New York	06/2009
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2010
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2011

UCLA State-of-the-Art Urology 03/2012
UCLA
Marina del Rey, California

Comprehensive Review Course in Female Pelvic Medicine and Reconstructive Surgery 04/2013
Dallas, Texas

AUA Hands-On Ultrasound Training Course 10/2014
Rochester, Minnesota

Certifications

Board Certifications

American Board of Urology

Urology 2002 - Present

Urology/Female Pelvic Medicine and Reconstructive Surgery 08/2013 - Present

Honors/Awards

AUA Resident Award - John D. Silbar North Central Section 10/1998

Urology Grant Recipient - Pfizer Scholars 01/1999

DeWeerd Travel Award Recipient 06/1999

Annual Audio-Visual Award - AUA - American Urological Association, Washington, District of Columbia 05/2011

Small intestinal submucosa urethral wrap as a salvage treatment option following multiple failed artificial urinary sphincters - Third Prize - Landon Trost, Daniel Elliott

Best Reviewer in 2011 Award - Urodynamics/Incontinence/Female Urology/Neurourology - The Journal of Urology 05/2012

Best Reviewer in 2012 Award - Urodynamics/Incontinence/Female Urology/Neurourology - The Journal of Urology 05/2013

Annual Audio-Visual Award - AUA - American Urological Association, San Diego, California 05/2013

Long-Term Outcomes of Patients Undergoing the Standard Versus Modified (5 Points of Fixation, 1 Point of Plication) Technique for Virtue Male Sling Placement - First Honorable Mention - Landon Trost, Daniel Elliott

Previous Professional Positions and Major Appointments

Senior Associate Consultant - Department of Urology, Mayo Clinic, Rochester, Minnesota 07/2000 - 06/2003

Assistant Professor of Urology - Mayo Clinic College of Medicine 04/2002 - 12/2012

Professional & Community Memberships, Societies and Services

Professional Memberships & Services

American Medical Association

Member 1991 - 2001

American Association of Clinical Urologists

Member 1998 - 2005

American Urological Association

Member 2000 - Present

International Continence Society

Member	2001 - Present
Society for Urodynamics & Female Urology	
Member	2002 - Present
Education Committee	
Committee Member	08/2014 - Present
Minnesota Medical Association	
Member	2002 - Present
Zumbro Valley Medical Society	
Member	2002 - Present
Olmsted County Medical Association	
Member	2002 - Present
International Urogynecologic Society	
Member	2003 - Present
Society of Urologic Prosthetic Surgeons	
Member	2005 - Present
Society of Laparoendoscopic Surgeons	
Member	2005 - Present
Minimally Invasive Robotic Association	
Member	2005 - Present
Minnesota Urological Society	
Member	2006 - Present
European Association of Urology	
International Member	03/2013 - Present
Section of Genitourinary Reconstructive Surgeons	
International Member	03/2013 - Present
Committee Member	04/2014 - Present
Section of Female and Functional Urology	
International Member	04/2013 - Present
International Urogynecologic Association	
Member	05/2013 - Present
International Pelvic Pain Society	
Member	05/2014 - Present

Journal Responsibilities

Journal Editorial Responsibilities

Journal of Robotic Surgery	
Consulting Editor	
Journal of Gynecology and Obstetrics	
Editorial Board Member	

Journal Other Responsibilities

Mayo Clinic Proceedings	
Reviewer	
Neurourology and Urodynamics	

Reviewer

The Journal of Urology

Reviewer

Journal of Investigative Urology

Reviewer

Nature Clinical Practice Urology

Reviewer

Mayo Clinic Health Letter

Reviewer

Archives of Gynecology and Obstetrics

Reviewer

Journal of Endourology

Reviewer

European Journal of Obstetrics & Gynecology and Reproductive Biology

Reviewer

Cleveland Clinic Journal of Medicine

Reviewer

Contemporary Clinical Trials

Reviewer

International Urogynecology Journal

Reviewer

Canadian Urological Association Journal

Reviewer, Canada

Urologia Internationalis

Reviewer

Educational Activities

Teaching Intramural

Prostate Pathology 03/2005
Mayo Medical School
Rochester, Minnesota

Institutional/Departmental Administrative Responsibilities, Committee Memberships and Other Activities

Mayo Clinic in Rochester

Department of Urology

Education Committee

Committee Member 02/2003 - 11/2008

Committee Member 10/2013 - Present

Presentations Extramural

National/International

Invited

Robotic Urogynecologic Surgery 03/2008
3rd Annual World Robotic Urology Symposium
Orlando, Florida

Robotic Sacrocolpopexy 01/2009
2009 International Robotic Urology Symposium (IRUS), Henry Ford Health System
Las Vegas, Nevada

Current Status Robotic GYN Surgery 01/2010
2010 International Robotic Urology Symposium (IRUS), Henry Ford Health System
Las Vegas, Nevada

Robotic Sacrocolpopexy 09/2010
28th World Congress on Endourology and SWL
Chicago, Illinois

Female Urology 09/2010
28th World Congress on Endourology and SWL
Chicago, Illinois

Optimizing Quality of Life With Regard to Urologic Function After Sacrectomy 01/2013
The 4th Annual Sacral Tumor Study Group Conference, Massachusetts General Hospital
Boston, Massachusetts

Treatment of Bladder and Urethral Mesh Erosion: Remove and Reconstruct 02/2015
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)
Scottsdale, Arizona

Oral

Long Term Follow-Up of Endoscopically Treated Upper Tract Transitional Cell Carcinoma 04/1995
American Urological Association Annual Meeting
Las Vegas, Nevada

Transabdominal Enzymatic Ablation of the Prostate in the Canine Model: Evaluation for Use for the Treatment of Outflow Obstruction Due to Benign Prostatic Hyperplasia 05/1996
Urodynamics Subsection Meeting, American Urological Association
Orlando, Florida

Long Term Analysis of 323 AMS 800 Artificial Urinary Sphincters 05/1996
Urodynamics Subsection Meeting, American Urological Association
Orlando, Florida

Analysis of Functional Durability of AMS 800 Artificial Urinary Sphincter: The Mayo Clinic Results 04/1997
American Urological Association Annual Meeting
New Orleans, Louisiana

Long Term Follow-Up Primary Realignment of Urethral Disruption Following Pelvic Fracture 04/1997
American Urological Association Annual Meeting
New Orleans, Louisiana

Does Reoperation on an Artificial Urinary Sphincter Increase the Likelihood for Further Reoperations for Mechanical or Nonmechanical Failure? American Urological Association Annual Meeting San Diego, California	06/1998
Is Nephroureterectomy Necessary in All Cases of Upper Tract Transitional Cell Carcinoma? Long Term Results of Conservative Endourology Management of Upper Tract Transitional Cell Carcinoma in Individuals with Normal Contralateral Kidneys American Urological Association Annual Meeting Dallas, Texas	05/1999
Durability of Cadaveric Pubovaginal Sling American Urological Association Annual Meeting Anaheim, California	06/2001
Does the Addition of Antibiotic Prophylaxis to CIC Alter the Incidence of UTI? American Urological Association Annual Meeting Orlando, Florida	06/2002
Surgical Approach for Placement of SPARC Suburethral Sling North Central Section, American Urological Association Chicago, Illinois	10/2002
SPARC suburethral sling: technique and results (Video Presentation) Western Section, American Urological Association Kauai, Hawaii	11/2002
Robotic laparoscopic sacrocolpopexy: new surgical technique for the treatment of vaginal vault prolapse (Video Presentation) American Urological Association Chicago, Illinois	04/2003
Colloquium-ICS/IUGA 2004 Paris, France	08/2004
Robotic-Assisted Laparoscopic Management of Vaginal Vault Prolapse Minimally Invasive Robotics Association Innsbruck, Austria	12/2005
Advancement in Salvage Procedure Following Failed Artificial Urinary Sphincter: Tandem Transcorporal Artificial Urinary Sphincter Cuff Technique (Video Presentation) American Urological Association Atlanta, Georgia	05/2006
Tandem Transcorporal Artificial Urinary Sphincter Cuff Salvage Technique Following Previous Cuff Erosion and Infection: Surgical Description and Outcome Western Section, American Urological Association Maui, Hawaii	10/2006
Assessment of Durability of Robotic Sacrocolpopexy for the Treatment of Vaginal Vault Prolapse Minimally Invasive Robotics Association New York, New York	01/2007
Minimally Invasive Advances: Stress Incontinence Mayo Clinic Rochester, Department of Urology Kohala Coast, Hawaii	02/2007

Treatment Options for the Failed Sling Mayo Clinic Rochester, Department of Urology Kohala Coast, Hawaii	02/2007
American Urological Association Annual Meeting Anaheim, California	05/2007
Robotics use in Gynecology: the Mayo Clinic experience Robotic Surgery: Facts or Fiction? Milano, Italy	06/2007
Indication and Management of Artificial Urinary Sphincter 7th Osijek Urological Days Osijek, Croatia	10/2007
Robotics Use in Gyenocology 7th Osijek Urological Days Osijek, Croatia	10/2007
Robotic Urogynecologic Surgery 3rd Annual World Robotic Urlogy Symposium Orlando, Florida	03/2008
Latest Advances and Treatment of Complications in Minimally Invasive Treatments for Stress Incontinence American Urological Association (AUA) Orlando, Florida	05/2008
Severe, recurrent bladder neck contracture after prostatectomy: Salvage with urethral wall stent(Video and Poster Presentation) American Urological Association (AUA) Orlando, Florida	05/2008
Surgical Advances of Stress Urinary Incontinence Indian American Urological Association (IAUA) Orlando, Florida	05/2008
Robotic Sacrocolpopexy International Robotic Urology Symposium, Henry Ford Health System Las Vegas, Nevada	01/2009
Overactive Bladder: Current Concepts of Management Mayo Clinic, Department of Urology, Rochester Meeting Kona, Hawaii	02/2009
Minimally Invasive Advances: Stress Incontinence Mayo Clinic, Department of Urology, Rochester Meeting Kona, Hawaii	02/2009
Management of Complications Following Anti-Incontinence Procedures Mayo Clinic, Department of Urology, Rochester Meeting Kona, Hawaii	02/2009
American Urological Association (AUA) Chicago, Illinois	04/2009
Robotic repair for vaginal prolapse has significant benefits North Central Section of the AUA - 83rd Annual Meeting Scottsdale, Arizona	11/2009

Current Status Robotic GYN Surgery International Robotic Urology Symposium, Henry Ford Health System Las Vegas, Nevada	01/2010
Robotics for Female Pelvic Reconstruction: Who, When and What? American Urological Association (AUA) San Francisco, California	05/2010
Results of Urethral Wrap As Salvage Treatment Option Following Multiple Failed Artificial Urinary Sphincters North Central Section of the AUA Chicago, Illinois	09/2010
Small intestinal submucosa urethral wrap as a salvage treatment option following multiple failed artificial urinary sphincters Audio-Visual American Urological Association (AUA) Washington, District of Columbia	05/2011
Long-Term Results of Small Intestinal Submucosa at Artificial Urinary Sphincter Placement for Management of Persistent / Recurrent Incontinence Following Multiple Sphincter Failures and Erosions North Central Section of the AUA Rancho Mirage, California	10/2011
OAB Current Concepts and Management Mayo Clinic Reviews in Urology Kohala Coast, Hawaii	02/2012
Treatment and Evaluation of the Complicated Artificial Urinary Sphincter Patient Mayo Clinic Reviews in Urology Kohala Coast, Hawaii	02/2012
Transvaginal Mesh Kits Complications and Alternatives Mayo Clinic Reviews in Urology Kohala Coast, Hawaii	02/2012
Vaginal Mesh for POP: what's the data show? American Urological Association (AUA) Atlanta, Georgia	05/2012
How do different centres perform Robot-assisted-Sacrocolpopexy? 4th Annual Society of European Robotic Gynecological Surgery (SERGS) Marseille, France	06/2012
Comparative Surgical Complications of the Robotic Sacrocolpopexy for Pelvic Organ Prolapse vs. Traditional Transabdominal Sacrocolpopexy European Robotic Urology Symposium (ERUS) London, United Kingdom	09/2012
Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013

Robotic Transvesical Rectourethral Fistula Repair Following a Robotic Radical Prostatectomy (Video Presentation) Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
Impact of Patient Obesity on Robotic Sacrocolpopexy for the Treatment of Vaginal Vault Prolapse Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
Long-Term Outcomes of Patients Undergoing the Standard Versus Modified (5 Points of Fixation, 1 Point of Plication) Technique for Virtue Male Sling Placement (Video Presentation) American Urological Association (AUA) San Diego, California	05/2013
Robotic Transvesical Rectourethral Fistula Repair Following a Robotic Radical Prostatectomy (Video Presentation) American Urological Association (AUA) San Diego, California	05/2013
Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas American Urological Association (AUA) San Diego, California	05/2013
The Impact of InhibiZone on Artificial Urinary Sphincter Infection Rate American Urological Association (AUA) San Diego, California	05/2013
Impact of Patient Obesity on Robotic Sacrocolpopexy for the Treatment of Vaginal Vault Prolapse American Urological Association (AUA) San Diego, California	05/2013
Long Term Risk for Repeat Anti-Incontinence Surgery following Urethrolysis: A Review of 100 Patients American Urological Association (AUA) San Diego, California	05/2013
Impact of patient obesity on robotic sacrocolpopexy for the treatment of vaginal vault prolapse 3rd International Meeting "Challenges in Endourology & Functional Urology" Paris, France	06/2013
Long-Term Outcomes for Artificial Urinary Sphincter Reimplantation Following Prior Device Explantation for Erosion and/or Infection South Central Section of the AUA Chicago, Illinois	09/2013
Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU Tübingen, Germany	10/2013

Long-term impact of artificial urinary sphincter reimplantation following prior device explantation for erosion and/or infection 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU Tübingen, Germany	10/2013
Impact of patient obesity on robotic sacrocolpopexy for the treatment of vaginal vault prolapse 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU Tübingen, Germany	10/2013
Long-Term Device Outcomes for Artificial Urinary Sphincter Reimplantation Following Prior Explantation for Erosion or Infection Society of Urodynamics Female Pelvic Medicine & Urogenital Reconstruction Miami, Florida	02/2014
Risk Factors for Intraoperative Conversion During Robotic Sacrocolpopexy Society of Urodynamics Female Pelvic Medicine & Urogenital Reconstruction Miami, Florida	02/2014
Results of artificial urinary sphincter reimplantation following previous erosion and/or infection 29th Annual Congress of the European Association of Urology Stockholm, Sweden	04/2014
Autologous Transobturator Mid-Urethral Sling Placement: A Novel Outpatient Procedure for Female Stress Urinary Incontinence (Video Presentation) American Urological Association (AUA) Orlando, Florida	05/2014
Surgical Management of Female Benign Urethral Stricture Disease: A Ten Year Experience American Urological Association (AUA) Orlando, Florida	05/2014
Urethral Management at the Time of Artificial Urinary Sphincter Erosion, Is Urethral Catheterization Alone Enough? North Central Section of the American Urological Association (AUA) Chicago, Illinois	09/2014
Autologous Transobturator Mid-Urethral Sling Placement for Female Stress Urinary Incontinence (Video Presentation) North Central Section of the American Urological Association (AUA) Chicago, Illinois	09/2014

Poster

Robot-Assisted Laparoscopic Sacrocolpopexy for Treatment of High Grade Vaginal Vault Prolapse: Surgical Technique and Initial Experience 29th Congress of the Societe Internationale d'Urologie Paris, France	09/2007
Robot Sacrocolpopexy: A Review of the Learning Curve in Fifty Casesl 4th World Congress on Controversies in Urology (CURy) Paris, France	01/2011
Impact of Radiotherapy on Surgical Repair and Outcomes in Patients with Rectourethral Fistula. 67th Annual Meeting of the Canadian Urological Association Alberta, Canada	06/2012

Term Device Outcomes for Artificial Urinary Sphincter Reimplantation Following Prior Explantation for Erosion or Infection
American Urological Association (AUA)
Orlando, Florida — 05/2014

Factors Associated with Intraoperative Conversion During Robotic Sacrocolpopexy
North Central Section of the American Urological Association (AUA)
Chicago, Illinois — 09/2014

Regional

Invited

Rectocele
Office of Women's Health brown bag
Rochester, Minnesota — 10/2004

Incontinence and Other Urological Issues
Radio Broadcast, Hosted by Dr. Thomas Shives
HealthLine - KROC Radio
Rochester, Minnesota — 08/2007

A Practical Approach to Treating Incontinence
Clinical Reviews, Rochester Civic Center
Rochester, Minnesota — 10/2008

A Practical Approach to Treating Incontinence
Clinical Reviews, Rochester Civic Center
Rochester, Minnesota — 11/2008

Incontinence and Other Urological Issues
Radio Broadcast, Hosted by Dr. Thomas Shives
Medical Edge Weekend - KROC Radio
Rochester, Minnesota — 03/2010

Urinary Incontinence
Radio Broadcast, Hosted by Dr. Thomas Shives
Medical Edge Weekend - KROC Radio
Rochester, Minnesota — 03/2011

Incontinence: Causes and Treatments
Prostate Cancer Support Group
Rochester, Minnesota — 02/2013

Urinary Incontinence
Radio Broadcast, Hosted by Dr. Thomas Shives
Medical Edge Weekend - KROC Radio
Rochester, Minnesota — 05/2014

Oral

Paratesticular Angiomyofibroblastoma
North Central Section, American Urological Association
Minneapolis, Minnesota — 09/1995

Does the Degree of Preoperative Elevation PSA Exclude a Patient for Consideration for Radical Retropubic Prostatectomy?
North Central Section, American Urological Association
Tucson, Arizona — 10/1996

Does Reoperation of an Artificial Sphincter Place the Patient at an Increased Risk for Subsequent Reoperation North Central Section, American Urological Association Amelia Island, Florida	10/1998
Is Fascia Lata Allograft Material Trustworthy for Pubovaginal Sling Repair North Central Section, American Urological Association Phoenix, Arizona	10/2000
Combined Stent and Artificial Urinary Sphincter for Management of Severe Recurrent Bladder Neck Contractures and Stress Incontinence after Prostatectomy: A Long-Term Evaluation. North Central Section, American Urological Association Phoenix, Arizona	10/2000
Does Nocturnal Deactivation of the Artificial Urinary Sphincter Lessen the Risk for Urethral Atrophy? North Central Section, American Urological Association Phoenix, Arizona	10/2000
Robotics Surgery for Vaginal Prolapse Controversies in Women's Health Symposium 2007 Nisswa, Minnesota	06/2007

Research Grants Awarded

Completed Grants

Federal

Co-Investigator	Selenium and Vitamin E Cancer Prevention Trial (SELECT). Funded by National Cancer Institute. (U10 CA 37429-SELECT)	01/2010 - 12/2010

Industry

Principal Investigator	Are There Histological and Tensile Strength Variations in Autologous, Allograft and SIS Pubovaginal Slings Over Time Using the Rabbit Model. Funded by Mentor Corporation. (MENTOR #5, 1A4575)	10/2002 - 09/2003
Co-Investigator	Single Looped Mechanical Urinary Sphincter: Determination of Required Urethral Constriction Forces to Provide Adequate Urinary Continence in the Canine Model. Funded by Dacomed, Inc. (Dacomed #1)	10/1995 - 12/1995
Co-Investigator	Clinical Investigation of the Safety and Performance of Timm Medical Technologies' Artificial Urinary Sphincter (TIMM-AUS). Funded by Timm Medical Technologies. (Timm # 1)	06/1999 - 02/2005
Co-Investigator	A Randomized, Double-Blind, Parallel-Group Study to Investigate the Effects of a Single Oral Dose of L-753099 Compared to Placebo and Tolerodine on Urodynamic Parameters in Healthy Male Volunteers. Funded by Merck & Co., Inc. (Merck 138)	07/1999 - 12/2003
Co-Investigator	The Safety, Local Tolerability, Pharmacokinetics, and Risk Benefit of Oxybutynin Transvaginal Rings (TVR) in Women with a History of Overactive Bladder. Funded by Advanced Biologics. (BIOLOGICS #1)	01/2001 - 12/2003

Co-Investigator	An Eight-Week, Double-Blind, Randomized, Parallel Group Design, Multicenter Study of FLOMAX Capsules, 0.4 mg Daily Vs. Placebo, in Female Patients w/ Lower Urinary Tract Symptoms (LUTS) w/ a Significant Component of Voiding Symptoms. Funded by Boehringer Ingelheim. (BOEHRINGER #34)	06/2001 - 07/2003
Co-Investigator	Veritas Collagen Matrix Urological Sling Postmarketing Clinical Study Protocol. Funded by Bio-Vascular, Inc. (BIOVASCULAR #1)	10/2001 - 09/2003

Mayo Clinic

Principal Investigator	Transurethral Enzymatic Ablation of the Prostate (TEAP); Short-term Concentration Study. Funded by Department Discretionary Funds. (Immuno 2)	09/1995 - 12/2003

Bibliography

Peer-reviewed Articles

1. Gleason PE, **Elliott DS** , Zimmerman D, Smithson WA, Kramer SA. Metastatic testicular choriocarcinoma and secondary hyperthyroidism: case report and review of the literature. J Urol. 1994 Apr; 151(4):1063-4. PMID:8126794.

2. **Elliott DS** , Blute ML, Patterson DE, Bergstralh EJ, Segura JW. Long-term follow-up of endoscopically treated upper urinary tract transitional cell carcinoma. Urology. 1996 Jun; 47(6):819-25. PMID:8677570. DOI:10.1016/S0090-4295(96)00043-X.

3. **Elliott DS** , Barrett DM. Long-term followup and evaluation of primary realignment of posterior urethral disruptions. J Urol. 1997 Mar; 157(3):814-6. PMID:9072573.

4. **Elliott DS** , Barrett DM. The artificial urinary sphincter in the female: indications for use, surgical approach and results. Int Urogynecol J Pelvic Floor Dysfunct. 1998; 9(6):409-15. PMID:9891964.

5. **Elliott DS** , Barrett DM. Mayo Clinic long-term analysis of the functional durability of the AMS 800 artificial urinary sphincter: a review of 323 cases. J Urol. 1998 Apr; 159(4):1206-8. PMID:9507835.

6. Brown JA, **Elliott DS** , Barrett DM. Postprostatectomy urinary incontinence: a comparison of the cost of conservative versus surgical management. Urology. 1998 May; 51(5):715-20. PMID:9610584.

7. **Elliott DS** , Barrett DM. The artificial genitourinary sphincter. Digital Urology Journal. 1998 Jul.

8. **Elliott DS** , Timm GW, Barrett DM. An implantable mechanical urinary sphincter: a new nonhydraulic design concept. Urology. 1998 Dec; 52(6):1151-4. PMID:9836575.

9. **Elliott DS** , Boone TB. Urethral devices for managing stress urinary incontinence. Journal of Endourology. 2000 Feb; 14(1):79-83. PMID:10735576.

10. **Elliott DS** , Barrett DM. Artificial urinary sphincter implantation using a bulbous urethral cuff: perioperative care. Urol Nurs. 2000 Apr; 20(2):89-90, 95-8. PMID:11998129.

11. Frank I, **Elliott DS** , Barrett DM. Success of de novo reimplantation of the artificial genitourinary sphincter. J Urol. 2000 Jun; 163(6):1702-3. PMID:10799164.

12. Petrou SP, **Elliott DS** , Barrett DM. Artificial urethral sphincter for incontinence. Urology. 2000 Sep 1; 56(3):353-9. PMID:10962293.

13. **Elliott DS** , Boone TB. Is fascia lata allograft material trustworthy for pubovaginal sling repair? Urology. 2000 Nov 1; 56(5):772-6. PMID:11068297.

14. **Elliott DS** , Boone TB. Recent advances in the management of the neurogenic bladder. Urology. 2000 Dec 4; 56(6 Suppl 1):76-81. PMID:11114567.

15. **Elliott DS** , Boone TB. Combined stent and artificial urinary sphincter for management of severe recurrent bladder neck contracture and stress incontinence after prostatectomy: a long-term evaluation. J Urol. 2001 Feb; 165(2):413-5. PMID:11176385. DOI:10.1097/00005392-200102000-00014.

16. **Elliott DS** , Mutchnik S, Boone TB. The "bends" and neurogenic bladder dysfunction. Urology. 2001 Feb; 57(2):365. PMID:11182361.

17. Kim IY, **Elliott DS** , Husmann DA, Boone TB. An unusual presenting symptom of sarcoidosis: neurogenic bladder dysfunction. J Urol. 2001 Mar; 165(3):903-4. PMID:11176503.

18. Petrou SP, **Elliott DS** . Artificial urethral sphincter for incontinence in adults. Drugs Today (Barc) 2001 Apr; 37(4):237-244. PMID:12768224.

19. **Elliott DS** , Barrett DM, Gohma M, Boone TB. Does nocturnal deactivation of the artificial urinary sphincter lessen the risk of urethral atrophy? Urology. 2001 Jun; 57(6):1051-4. PMID:11377302.

20. **Elliott DS** , Segura JW, Lightner D, Patterson DE, Blute ML. Is nephroureterectomy necessary in all cases of upper tract transitional cell carcinoma? Long-term results of conservative endourologic management of upper tract transitional cell carcinoma in individuals with a normal contralateral kidney. Urology. 2001 Aug; 58(2):174-8. PMID:11489692.

21. Lightner DJ, **Elliott D** , Gillett M. Surgeon's corner. Transvaginal culdoplasty for posthysterectomy vaginal vault prolapse. Contemp Urol. 2003 Sep; 15(9):15-22.

22. DiMarco DS, **Elliott DS** . Tandem cuff artificial urinary sphincter as a salvage procedure following failed primary sphincter placement for the treatment of post-prostatectomy incontinence. J Urol. 2003 Oct; 170(4 Part 1):1252-4. PMID:14501735.

23. **Elliott DS** , Barrett DM. Current indications for the use of the artificial genitourinary sphincter and management of its complications. The Scientific World Journal. 2004; 4(S1):114-27.

24. Di Marco DS, Chow GK, Gettman MT, **Elliott DS** . Robotic-assisted laparoscopic sacrocolpopexy for treatment of vaginal vault prolapse. Urology. 2004 Feb; 63(2):373-6. PMID:14972496. DOI:10.1016/j.urology.2003.09.033.

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30. **Elliott DS** , Krambeck AE, Chow GK. Long-term results of robotic assisted laparoscopic sacrocolpopexy for the treatment of high grade vaginal vault prolapse. J Urol. 2006 Aug; 176(2):655-9.

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32. **Elliott DS** , Chow GK. [Management of vaginal vault prolapse repair with robotically-assisted laparoscopic sacrocolpopexy]. Ann Urol (Paris) 2007 Feb; 41(1):31-6. PMID:17338498.

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38. Thompson RH, Krambeck AE, Lohse CM, **Elliott DS** , Patterson DE, Blute ML. Endoscopic management of upper tract transitional cell carcinoma in patients with normal contralateral kidneys. Urology. 2008 Apr; 71(4):713-7. Epub 2008 Feb 11. PMID:18267338. DOI:10.1016/j.urology.2007.11.018.

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incontinence following multiple prior sphincter failures and erosions. Urology. 2012 Apr; 79(4):933-8. Epub 2011 Nov 25. PMID:22119252. DOI:10.1016/j.urology.2011.09.003.

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Non-peer-reviewed Articles

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EXHIBIT 2

FEE SCHEDULE

Fee schedule is $700/hour

EXHIBIT 3

TESTIMONY HISTORY

Coloplast A/S v. Generical Medical Devices; United States District Court, Western District of Washington at Tacoma, Case No. C10-227BHS (April 2012)

Linda Gross et al. vs. Gynecare, et al.; Superior Court of New Jersey Law Division Middlesex County Case No. MID-L-9131-08 (November 2013)

Diane Bellew vs. Ethicon, et al. United States District Court, Southern District of West Virginia, Case No. 2:13-cv-22473 (September 2014)